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REVOLUTIONIZING INTERVENTIONAL MEDICINE

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FINANCIAL

STEREOTAXIS



Stereotaxis' goal is to establish a new standard of care for interventional medicine by enabling the treatment of more complex cases so as to provide patients and care givers with less invasive alternatives, and by increasing the efficiency and efficacy of conventional treatment.

We can achieve this through our ability to bring computer controlled precision and automation to interventional procedures, making it easier to accurately navigate and position interventional devices within the heart and other hard to access areas of the anatomy.

# DEAR SHAREHOLDERS:

This annual report marks our first year as a public company. We completed our IPO in August 2004, raising approximately \$41 million, net of expenses. This landmark event positions Stereotaxis for continued leadership in bringing remote computer control to interventional cardiology and electrophysiology, two of the fastest-growing segments of the medical device industry. Our reputation for technological innovation continues to build in the marketplace, and now, with the financial resources necessary to drive our business forward, Stereotaxis can complete its transition from a development stage company to a successful commercial enterprise.

2004 was a very significant year in Stereotaxis' evolution, as the Company recorded revenue of \$18.8 million in its first full-year of commercialization. We are clearly making progress in achieving our goal of establishing the Stereotaxis System as the standard of care for complex interventional procedures in cardiology. During the year, we placed 22 of our systems in leading hospitals throughout the world, bringing our total installed base to 30 systems. It is important to note that two-thirds of these systems have been placed at community or regional hospitals that tend to have a strong bottom line focus and one-third at academic or teaching institutions. We also sold two

community based regional hospitals their second system. In each case the first system was primarily intended for their electrophysiology departments and the second system will be used in their interventional cardiology practices. We believe these second system acquisitions are a strong endorsement of our value proposition. From an operating standpoint, we were able to achieve a significant increase in selling prices in 2004 and, coupled with our cost reduction efforts, achieved a gross margin of 52 percent for the second half of the year. Stereotaxis ended 2004 with purchase orders and commitments for its systems of approximately \$20 million. Thus we head into 2005 with significant momentum.

We intend to leverage the growing acceptance of our products by leading hospitals, physicians and patients, both by working with our industry partners, including Siemens AG Medical Solutions, Philips Medical Systems and Biosense Webster®, Inc., a Johnson & Johnson company, to increase clinical acceptance and by investing in our own internal sales and marketing infrastructure in order to penetrate the growing interventional markets, both in the U.S. and internationally. We achieved significant milestones relating to our strategic alliances in 2004 and early 2005. First, in 2004, we completed integration of our new Niobe® II system with Siemens' AXIOM Artis x-ray system closely followed by integration with Philips' Allura x-ray system.

## ACCOMPLISHMENTS:

- ☐ Completion of Initial Public Offering
- ☐ 30 systems installed by the end of our first full year of commercial operations
- ☐ \$20 million in order backlog
- ☐ Achievement of 52% gross margin in second half of year
- ☐ Sale of a second Stereotaxis System to two of our customers, both community based regional hospitals
- ☐ Integration with Siemens and Philips
- ☐ CE mark approval for Biosense Webster magnetically enabled catheters and CARTO™ XP system

Then, in early 2005, Biosense Webster received CE mark approval for its first two magnetically enabled catheters, as well as the integrated Stereotaxis CARTO XP advanced 3-D mapping and localization system, allowing us to commercialize these products in Europe.

Interventional procedures in cardiology, which typically offer a less invasive alternative to surgery, comprise one of the fastest growing areas of medicine today, driven by the demographics of aging populations and patient demand. Our vision is to make Stereotaxis the "Standard of Care" for cardiac interventional treatment by combining digital integration of advanced imaging technologies with computerized remote control of therapeutic devices, providing, for the very first time, image guided automation for interventional medicine and enabling highly accurate instrument navigation and control within areas of complex and tortuous anatomy.

Stereotaxis has successfully integrated its new Niobe system with the x-ray imaging equipment of both Siemens and Philips as well as with the CARTO XP electrophysiology mapping system of Biosense Webster. These important integration alliances provide a technologically advanced image guidance platform for our Niobe system, setting the stage for Stereotaxis to bring to market in 2005 and beyond advanced 3-D automation software and an expanded tool kit of magnetically

guided disposable devices focused on further simplifying complex procedures and bringing additional time savings and other economic benefits to standard cases. It is through our ability to deliver clinical value to every interventional case that we expect to achieve our vision for a new "Standard of Care".

With the support of our committed partners, we are focused on penetrating the large and growing interventional cardiology and electrophysiology markets. The cardiac cath lab represents one of the most important revenue and profit centers for a hospital today. In total, approximately 1.8 million interventional cardiology procedures and 800,000 electrophysiology procedures are performed each year worldwide. This procedure volume is growing as patients demand less invasive treatment, cost containment pressures mount, and the incidence of coronary artery disease and arrhythmias continues to rise in line with population demographics. We believe the Stereotaxis System represents an opportunity for hospitals to more effectively address the growing interventional market by providing their clinicians with the potential to expand procedure volume, handle more complex cases, standardize procedure times, improve efficiency, and lower disposable costs.

Potential customers for our system include approximately 6,000 interventional cardiology and electrophysiology labs worldwide. Each year, more than 800 cardiac cath labs are built or renovated,

representing our immediate market opportunity. Importantly, as the number of installed systems grows, revenues from related disposable interventional devices, software enhancements and service contracts are expected to grow in parallel.

Our ground-breaking technology has been validated through the strategic alliances we have formed with Siemens, Philips and Biosense Webster, three of the leading companies in the medical technology industry. Collaborations such as these not only provide validation of our technology, they also allow us to leverage the critical sales expertise, distribution channels and service capabilities of our top-tier partners. We are grateful to our current partners for their enthusiastic support for Stereotaxis and look forward to expanding these relationships, while continuing to seek new opportunities for additional strategic alliances in the field of interventional medicine — a key element of our growth strategy.

We firmly believe the technology Stereotaxis brings to the market has the potential to revolutionize the practice of interventional medicine and we are committed to further developing its value proposition. As such, we are engaged in numerous studies from simple data collection efforts to complex clinical trials to document the benefits of our system in terms of efficiency, safety and efficacy. Although we will continue to invest in research to develop the fullest scope of our cardiology applications and,



potentially, to expand our platform into the neuro-endovascular arena and other interventional disciplines, we remain focused on achieving break-even in the second half of 2006, an important step in building significant value for our shareholders. Stereotaxis starts 2005 as a stronger company, both commercially and financially, and we are on track to build on the successes achieved in 2004.

I would like to extend my sincerest thanks to our customers, shareholders and employees for their continued support, and look forward to reporting our company's successes in the year to come.

Sincerely,

Bevil J. Hogg  
President, Chief Executive Officer

**Stereotaxis'  
Senior Management Team**

*Standing (from left):*

Doug Bruce

Ruchir Sehra, M.D.

Mike Kaminski

Jim Stolze

Melissa Walker

*Seated:*

Bevil J. Hogg

# STEREOTAXIS INNOVATION IN

Interventional medicine, in which a flexible disposable instrument such as a catheter or guidewire, typically inserted through a needle puncture in the femoral artery is used to deliver therapy to areas of the body accessible through the circulatory system, is one of the fastest growing disciplines in medicine today. Worldwide, there are more than 2.6 million interventional procedures annually in cardiology alone, representing a \$12 billion market that is growing at roughly 12% per annum.

Interventional procedures, which often involve the placement of a stent to open and "scaffold" diseased vessels or the ablation of diseased tissues, are usually far less invasive than surgical alternatives, offering the patient shorter hospital stays and faster recovery times. Delivery of interventional therapy is typically done in an intervention room, sometimes called a "cath lab" in which a sophisticated x-ray fluoroscopy system is used to provide positional and other imaging information to the clinician who then must manually navigate a

long, flexible catheter or guidewire deep within the blood vessels to access the treatment site.

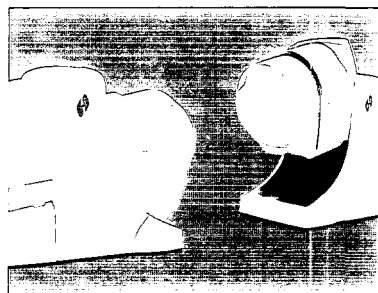
As the scope of interventional procedures expands, driven by patient demand for less invasive therapies, and by payers for less costly treatment and related recovery, the navigation of these devices, typically done manually, is becoming increasingly complex and time consuming, placing a burden on the clinician and constraining productivity. Without the support of the Stereotaxis system, the clinician must treat sicker, more complex patients often using conventional tools designed for much simpler procedures. This results in longer and less predictable procedure times.

Stereotaxis has, for the first time, introduced a more sensible approach that relies on computer controlled magnetic fields to articulate and remotely steer the interventional instrument, thereby obviating the mechanical compromises and inefficiencies inherent in manual navigation and allowing complete control and automation at the working end of the instrument. The result is a more efficient and effective means of delivering

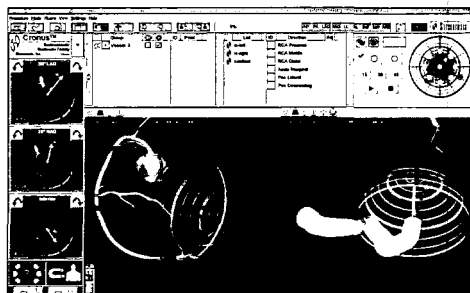
interventional medicine, one that has the potential to expand treatment into areas of highly complex and tortuous anatomy that have been inaccessible to most practitioners. The most important attributes of the system include distal, or working end device control, more flexible, softer and typically less expensive devices, and the wherewithal for specialized software to bring both accuracy and efficiency to increasingly complex interventional procedures.

The Stereotaxis Niobe system can also enable clinicians to perform many interventional procedures remotely, greatly reducing their x-ray exposure. Stereotaxis' initial focus is in the area of cardiac interventional medicine, more specifically interventional cardiology and electrophysiology, but the technology has the potential to remotely navigate flexible devices anywhere in the body, allowing for future platform expansion into new areas of interventional medicine, including the brain and other major organ systems.

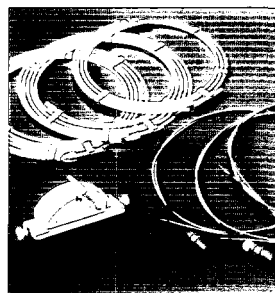
## Stereotaxis' Product Family Magnet Systems



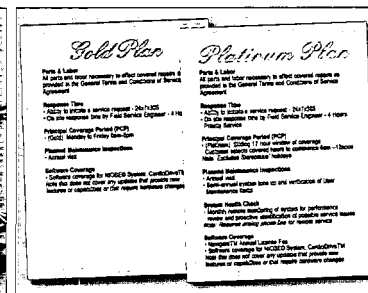
## Software



## Disposable Catheters and Guidewires

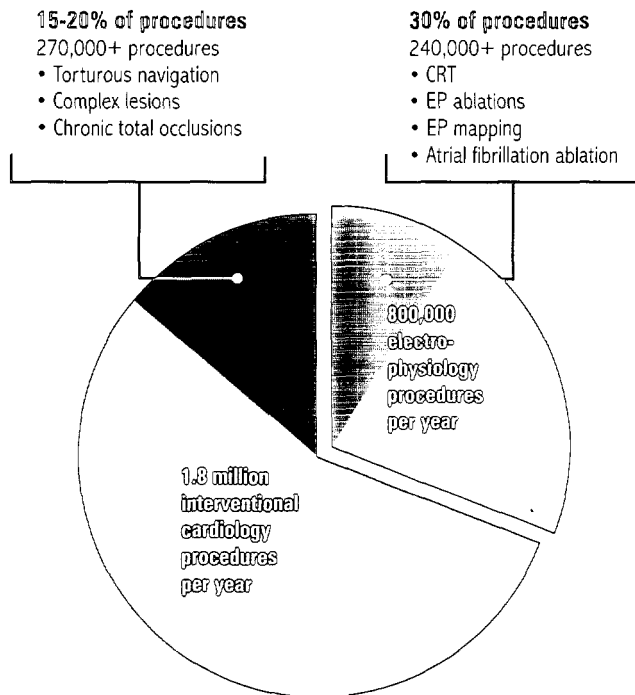


## Service



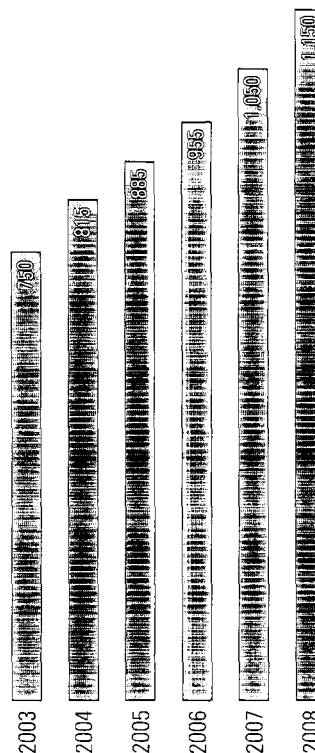
# INTERVENTIONAL MEDICINE

Stereotaxis is focused on the interventional cardiology and electrophysiology markets, and estimates that its technology can add value in over 500,000 of the more complex and time consuming cases among the 2.6 million annual procedures completed in these areas worldwide.



## Market Opportunity

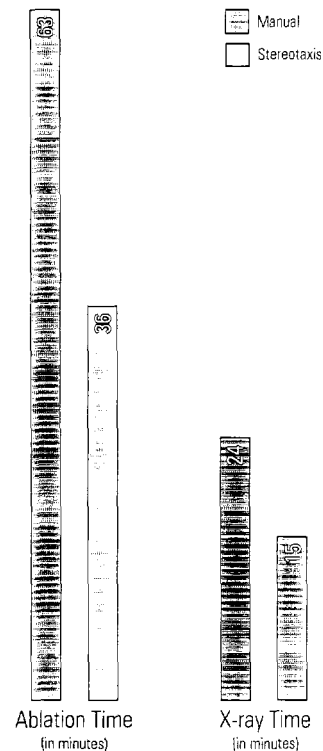
Projected number of Cath Lab installations per year



## Efficiency

Comparison of electrophysiology ablation and x-ray time using a Stereotaxis catheter vs. a standard manual catheter.

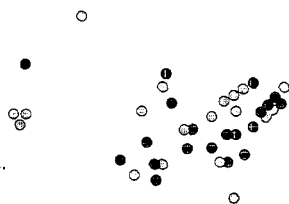
(FDA and Stereotaxis initial clinical trial data)



## Worldwide Distribution

We have sold or have on order more than 50 systems worldwide. Approximately two-thirds of these systems are in community hospitals, the remainder being at academic institutions.

- Sold
- On order

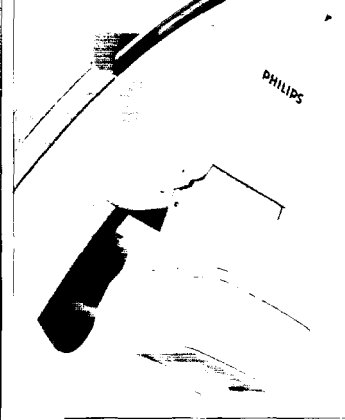
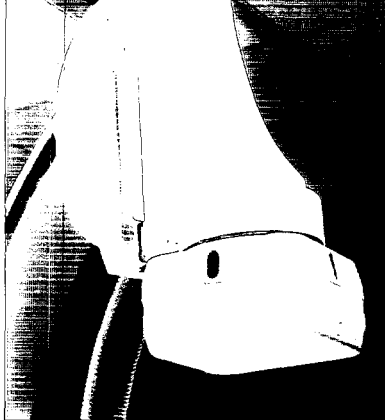
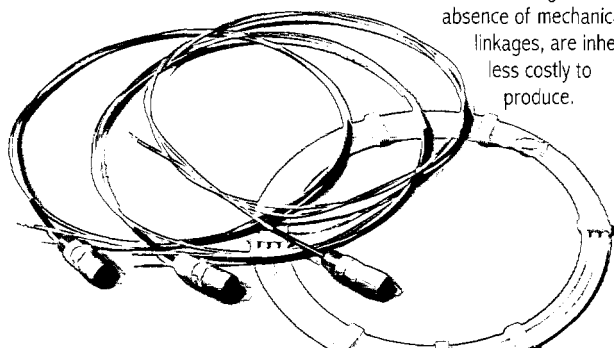


Traditionally, interventional procedures in cardiology have been performed by clinicians manually steering the distal or working end of a catheter or guidewire by manipulating the proximal end of the device. The Stereotaxis System consists of computer-controlled magnets, a sophisticated user interface, magnetically enabled guidewires and catheters, and a catheter advancer system. Computer controlled magnetic navigation provides the clinician with precise control directly at the working end of the interventional device, which can be operated either from the side of the patient table or, remotely, from a control room outside the x-ray field.

**Electrophysiology** Over four million people in the U.S. currently suffer from abnormal heart rhythms, known as arrhythmias. The most common interventional treatment for arrhythmias is an ablation procedure in which the diseased tissue causing the arrhythmia is isolated or destroyed. We believe the Stereotaxis system is particularly well suited for those procedures that are time consuming, unpredictable or can only be accomplished by highly experienced physicians.

**Interventional Cardiology** The advent of drug-eluting stents has allowed clinicians to undertake more complex cases that historically would have been treated with open-chest surgery. As a result of expanding the scope of interventional treatment, clinicians face increasingly complex navigational challenges, including tortuous lesions, calcific lesions and bifurcations, which we believe can be more effectively addressed using the Stereotaxis System.

Stereotaxis has developed a suite of disposable interventional catheters, guidewires and a catheter advancer for use with our system. In addition, pursuant to our agreement with Biosense Webster, Stereotaxis is co-developing a complete range of electrophysiology catheters that can be navigated with our system, the first two of which received European commercialization approval in early 2005. Compared to traditional manual catheters, these are more flexible devices and, reflecting the virtual absence of mechanical linkages, are inherently less costly to produce.



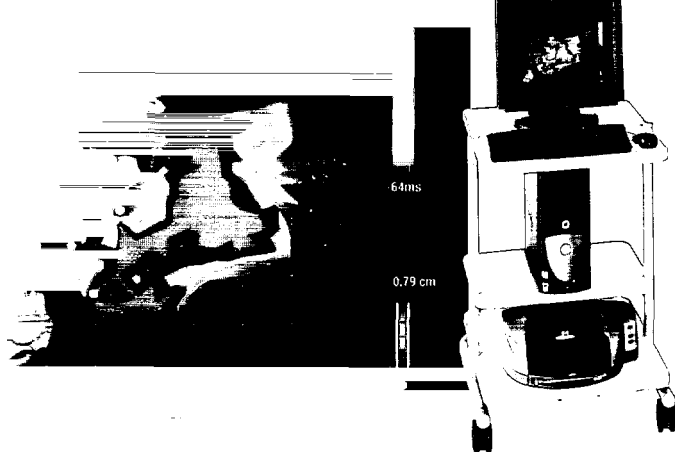
# STEREOTAXIS

**NIOBE Cardiology Magnet System** employs computerized magnet technology to remotely and precisely navigate catheters or guidewires through complex paths in the blood vessels and chambers of the heart to deliver treatment.

NIOBE II utilizes a tilt mechanism to expand imaging of anatomic structures. This model was commercialized in 2004.





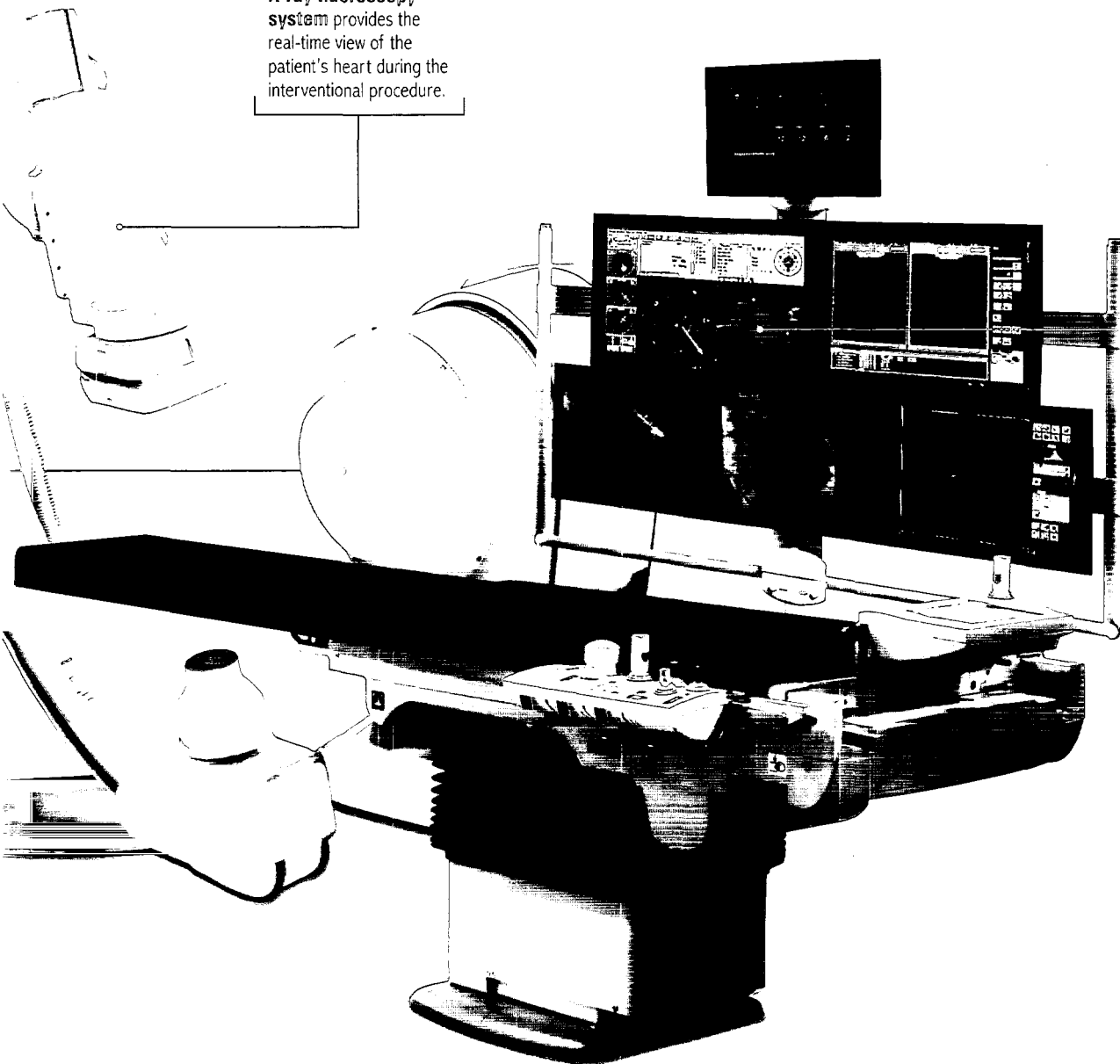


The Stereotaxis System is designed to be integrated with x-ray fluoroscopy systems, mapping and ablation localization systems and proprietary catheters and guidewires. Our strategic alliances with Siemens, Philips and Biosense Webster provide significant benefits to our customers and are an important endorsement of our value proposition.

# TECHNOLOGY

X-ray fluoroscopy system provides the real-time view of the patient's heart during the interventional procedure.

The Stereotaxis Niobe II system is shown here with the Siemens AXIOM Artis x-ray fluoroscopy system.



NAVIGANT is the advanced user interface, or physician control center, where procedures are visualized and tracked in order to provide the instrument control commands that govern the motion of the working tip of the catheter or guidewire.

Stereotaxis estimates that approximately 800,000 electrophysiology procedures are performed worldwide each year. Of these, we believe that roughly 30% are very time consuming or can only be performed by highly experienced physicians, and we believe that the number of these complex procedures is growing at a rate of approximately 12% per year. For electrophysiology clinicians, our system allows for more predictable and efficient navigation of disposable devices to treatment sites, including the left atrium for atrial fibrillation procedures. Accordingly, we believe our system will significantly lower the skill barriers required to perform complex electrophysiology procedures.

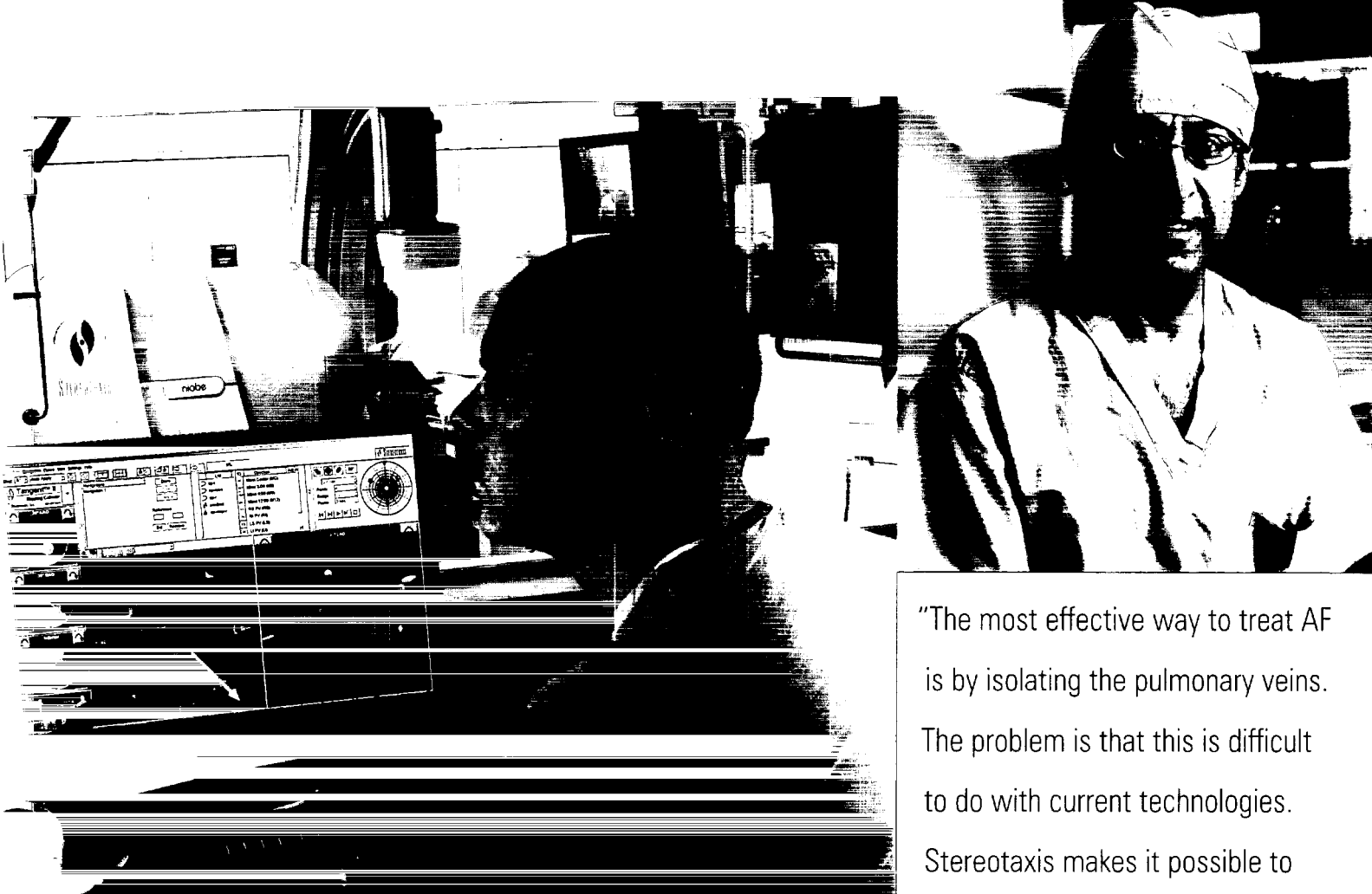
For hospital administrators, the standardization of electrophysiology procedure times achievable with the Stereotaxis System will allow for more efficient patient scheduling. In addition, we believe our technology can bring about improvements in cath lab productivity by more effectively and efficiently controlling the delivery of disposable devices resulting in reductions in consumables consumption as well as in overall procedure times. An added benefit to the clinician is the ability to perform the procedure from a control room, out of the x-ray field, without having to wear a heavy lead apron which would otherwise be required.

The Stereotaxis Niobe II system is shown here with the Philips Allura x-ray system at St. Elizabeth's Hospital in Boston, MA.

"The future of Electrophysiology is to effectively enable therapy delivery in complex cases such as AF and VT. We must replace the decade old tools we currently attempt to adapt to treat these cases. We need catheters that are flexible, go where we direct them, with tremendous precision, atraumatically, and with consistency. No other technology can accomplish what Stereotaxis can with a catheter."

Larry A Chinitz MD, FACP, FACC; Director, Cardiac Electrophysiology and Invasive Cardiology / Director, Heart Rhythm Center  
Associate Professor of Medicine, NYU School of Medicine; New York, NY





"The most effective way to treat AF is by isolating the pulmonary veins. The problem is that this is difficult to do with current technologies. Stereotaxis makes it possible to enable these more complex procedures because of the system's ability to precisely navigate a catheter."

**Charles I. Haffajee, MD;** Director, Cardiac Electrophysiology, Arrhythmia and Pacing / Professor of Medicine, Tufts University School of Medicine; Caritas St. Elizabeth's Medical Center; Boston, MA

# ELECTROPHYSIOLOGY

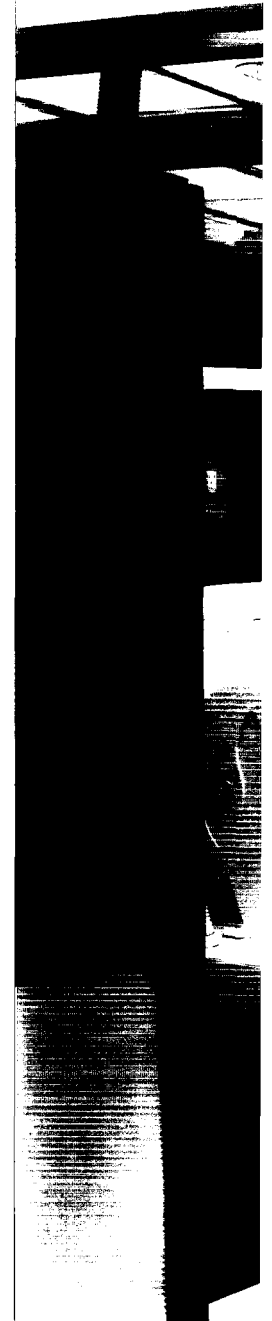
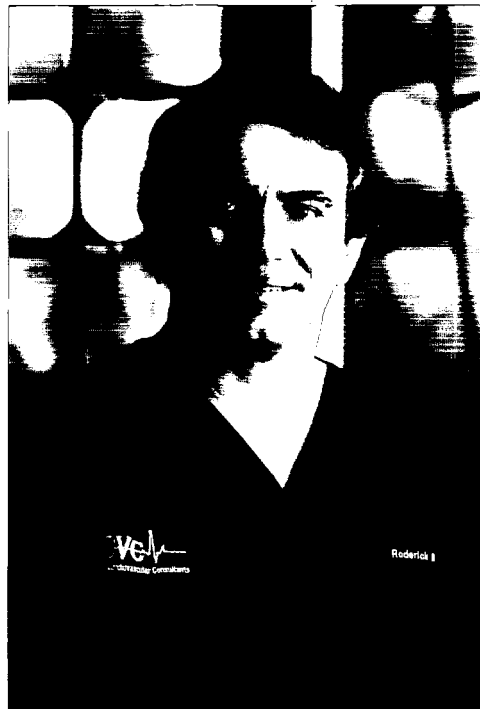
Nearly 500,000 people die annually from coronary artery disease. Physicians are currently performing approximately 1,000,000 interventional procedures yearly to open blocked vessels, and another 500,000 patients with especially complex or challenging coronary disease undergo open heart surgery to bypass blocked coronary arteries. Treatment in interventional cardiology procedures is effected by navigating a guidewire through a narrowing or partial blockage of the coronary arteries so as to deliver an expandable metal scaffold or stent to hold open the diseased vessel. However, in a significant subset of cases, the treatment site is located within especially difficult anatomy requiring the clinician to navigate the guidewire and stent delivery system through a complex series of vessel branches and turns as well as through the lesion itself. We believe that our system's ability to bring computer controlled precision and automation to the delivery of guidewires and other therapeutic devices can greatly simplify complex navigation and treatment in such cases.

We believe that the Stereotaxis System will enable interventional cardiologists to expand the scope of their practice, making possible a higher percentage of interventional approaches to cases that otherwise would have required surgery.

The Stereotaxis Niobe II system is shown here with the Siemens AXIOM Artis x-ray fluoroscopy system at Central Baptist Hospital in Lexington, KY.

"Patients who previously would have had bypass surgery are now being treated with drug eluting stents in an interventional manner. There is going to be a greater demand to take on more complex lesions and to deliver drug eluting stents into more difficult locations than ever before. We envision the Niobe system as a method of helping us to deliver therapy into more challenging areas of the coronary anatomy."

Roderick B. Meese, MD; Medical Director,  
Trinity Mother Frances Hospital; Tyler, TX



# INTERVENTIONAL CARD

"When you consider buying a piece of capital equipment, you ask yourself, 'What's this going to mean to us?' I can tell you that the payoff has been huge. I think that the Stereotaxis technology will be the technology that we'll want at

Central Baptist in every lab at this hospital."

**William G. Sisson**; President and CEO,  
Central Baptist Hospital; Lexington, KY.

(Central Baptist Hospital has acquired two Niobe systems.)

0 L O G Y

## Senior Management

---

**Bevil J. Hogg**

President,  
Chief Executive Officer

**Michael P. Kaminski**

Chief Operating Officer

**James M. Stolze**

Vice President and  
Chief Financial Officer

**Doug M. Bruce**

Senior Vice President,  
Research and Development

**Melissa Walker,  
M.S., RAC**

Vice President,  
Regulatory Affairs and  
Quality Systems

**Ruchir Sehra, M.D.**

Vice President, Clinical Affairs,  
and Chief Medical Officer

## Board of Directors

---

**Fred A. Middleton**

Chairman  
General Partner  
Sanderling Ventures

**Bevil J. Hogg**

President/CEO  
Stereotaxis, Inc.

**Abhi Acharya, Ph.D.**

Medical Device  
Industry Consultant

**Christopher Alafi, Ph.D.**

General Partner  
Alafi Capital Company, LLC

**John C. Aplin, Ph.D.**

General Partner  
CID Equity Partners

**David W. Benfer**

President/CEO  
St. Raphael Healthcare System

**Ralph G. Dacey, Jr., M.D.**

Chairman  
Department of Neurosurgery  
Washington University School  
of Medicine

**Gregory R. Johnson, Ph.D.**

Managing Director  
Prolog Ventures, LLC

**William M. Kelley**

Chairman  
Hill-Rom Company, Inc.

**Randall D. Ledford, Ph.D.**

Senior Vice President and  
Chief Technology Officer  
Emerson Electric Co.

**Abhijeet J. Lele**

General Partner  
EGS Healthcare Capital  
Partners

**William C. Mills III**

Managing Member  
EGS Healthcare Capital  
Partners

**David J. Parker**

General Partner  
Amersand Ventures

## Stockholder Information

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www.stereotaxis.com

**Transfer Agent  
and Registrar**

**The Bank of New York**  
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New York, NY 10286

**Independent Auditor****Ernst & Young**

190 Carondelet Plaza  
Suite 1300  
St. Louis, Missouri 63105

**Investor Relations****Noonan Russo**

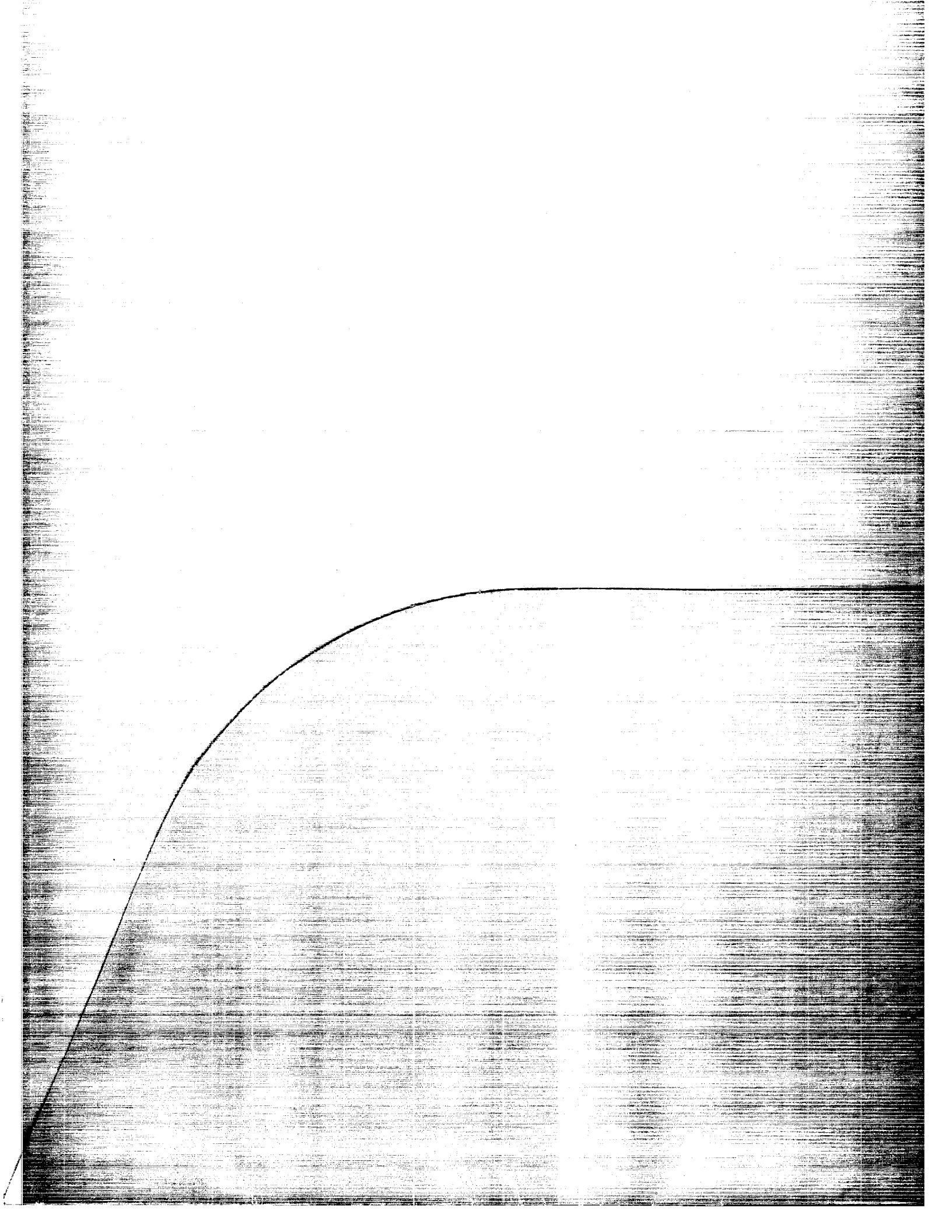
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New York, NY 10016  
Tel: 212-845-4269  
brian.ritchie@eurorscog.com

**Corporate Counsel****Bryan Cave LLP**

One Metropolitan Square  
211 North Broadway  
Suite 3600  
St. Louis, Missouri 63102-  
2750

**Annual Meeting**

The Annual Meeting of  
Shareholders will be held at  
9:00 am on May 11, 2005, at  
Stereotaxis corporate head-  
quarters at 4041 Forest Park  
Avenue; St. Louis, MO 63108





STEREOTAXIS

1000 Park Avenue

New York, New York 10021

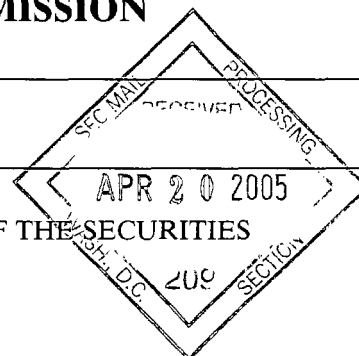
212.633.1000

www.stereotaxis.com



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 10-K**



(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 000-50884

**STEREOTAXIS, INC.**

(Exact name of Registrant as Specified in its Charter)

DELAWARE  
(State or Other Jurisdiction of Incorporation  
or Organization)

94-3120386  
(I.R.S. Employer  
Identification Number)

4041 Forest Park Avenue  
St. Louis, MO 63108  
(Address of Principal Executive Offices including Zip Code)

(314) 615-6940  
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.001 Par Value

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K, or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).  
Yes ☐ No ☒

The initial public offering of the registrant's common stock was completed on August 12, 2004, prior to which date there was no public market in the registrant's common equity.

The number of outstanding shares of the registrant's common stock on February 28, 2004 was 27,206,460.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the Registrant's next Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

**STEREOTAXIS, INC.**  
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## **PART I**

### **ITEM 1. BUSINESS**

#### **FORWARD-LOOKING STATEMENTS**

This annual report on Form 10-K, including the sections entitled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, contains forward-looking statements. These statements relate to, among other things:

- our business strategy;
- our value proposition;
- the ability of physicians to perform certain medical procedures with our products safely, effectively and efficiently;
- the adoption of our products by hospitals and physicians;
- the market opportunity for our products, including expected demand for our products;
- the timing and prospects for regulatory approval of our additional disposable interventional devices;
- our plans for hiring additional personnel;
- our estimates regarding our capital requirements; and
- any of our other plans, objectives, expectations and intentions contained in this annual report that are not historical facts.

These statements relate to future events or future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “could”, “expects”, “plans”, “intends”, “anticipates”, “believes”, “estimates”, “predicts”, “potential” or “continue” or the negative of such terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements are only predictions.

Factors that may cause our actual results to differ materially from our forward-looking statements include, among others, changes in general economic and business conditions and the risks and other factors set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors that May Affect Future Results” and elsewhere in this annual report on Form 10-K.

Our actual results may be materially different from what we expect. We undertake no duty to update these forward-looking statements after the date of this annual report, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

#### **Overview**

We design, manufacture and market an advanced cardiology instrument control system for use in a hospital’s interventional surgical suite, or “cath lab”, that we believe revolutionizes the treatment of coronary artery disease and arrhythmias by enabling important new therapeutic solutions and enhancing the efficiency and efficacy of existing catheter-based, or interventional, procedures. Our Stereotaxis System allows physicians to more effectively navigate proprietary catheters, guidewires and stent delivery devices, both our own and those we are co-developing

with strategic partners, through the blood vessels and chambers of the heart to treatment sites and then to effect treatment. This is achieved using computer-controlled, externally applied magnetic fields that precisely and directly govern the motion of the internal, or working, tip of the catheter, guidewire or stent delivery device. We believe that our Stereotaxis System represents a revolutionary technology in the cath lab, bringing precise remote digital instrument control and programmability to the cath lab, and has the potential to become the standard of care for a broad range of complex cardiology procedures.

We believe that our Stereotaxis System is the only technology to be commercialized that allows remote, computerized control of catheters, guidewires and stent delivery devices directly at their working tip. To our knowledge, we have no direct competitors in this field. We also believe that our technology represents an important advance in the ongoing trend toward digital instrumentation in the cath lab and provides substantial, clinically important improvements and cost efficiencies over manual interventional methods, which require years of physician training and often result in long and unpredictable procedure times and sub-optimal therapeutic outcomes.

We began commercial shipments in 2003, following U.S. and European regulatory approval of the core components of the Stereotaxis System, and had revenues of approximately \$18.8 million in 2004 and \$5.0 million in 2003. As of December 31, 2004, we had sold and delivered 30 Stereotaxis Systems, including 20 in the U.S. and 10 internationally, and physicians have used these systems to perform approximately 1,100 cardiology procedures. We also had purchase orders and other commitments for an additional \$20 million of our Stereotaxis Systems. There can be no assurance that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays.

The Stereotaxis System is designed primarily for the interventional treatment of coronary artery disease, or interventional cardiology, and for the interventional treatment of abnormal heart rhythms known as arrhythmias, or electrophysiology. Our Stereotaxis System consists of the following proprietary components:

- our NIOBE cardiology magnet system, which utilizes permanent magnets to navigate catheters, guidewires and stent delivery devices through complex paths in the blood vessels and chambers of the heart to carry out treatment;
- our NAVIGANT advanced user interface, or physician control center, which physicians use to visualize and track procedures and to provide instrument control commands that govern the motion of the working tip of the catheter, guidewire or stent delivery device;
- our CARDIODRIVE automated catheter advancer, which is used to remotely advance and retract the catheter in the patient's heart; and
- our suite of interventional catheters, guidewires and stent delivery devices, which we refer to as disposable interventional devices.

The Stereotaxis System is designed to be installed in both new and replacement cath labs worldwide. We currently have regulatory clearance to market our NIOBE cardiology magnet system, our NAVIGANT advanced user interface, our CARDIODRIVE automated catheter advancer and various disposable interventional devices in the U.S. and in the European Union, and we anticipate applying through Siemens and J&J to begin clinical trials in Japan in 2005. Current and potential purchasers of our Stereotaxis System include leading research and academic hospitals as well as medium and high volume commercial and regional medical centers around the world. We estimate that there are more than 750 new and replacement cardiology cath labs being installed worldwide each year. We also estimate that the initial imaging equipment and installation costs for a new or replacement cardiology cath lab today can range as high as \$2 million, for a total cardiology cath lab installation market potentially in excess of \$1.5 billion per year.

The market for cardiovascular medical devices worldwide exceeds \$12 billion per year and is estimated to be growing at 12% annually. Physicians are currently performing approximately 1.8 million interventional cardiology procedures and approximately 800,000 electrophysiology procedures worldwide each year. This procedure base continues to grow, due to patient demand for less invasive procedures, cost containment pressure and an increasing incidence of coronary artery disease and arrhythmias. While the Stereotaxis System potentially has broad applicability for many of these procedures, we believe that it can provide significant advantages relative to manual interventional methods for approximately 15% of interventional cardiology procedures, or approximately 270,000 procedures annually, including procedures for stent delivery and the treatment of complex lesions. In electrophysiology, we believe that the Stereotaxis System can provide significant advantages for approximately 30% of procedures, or about 240,000 procedures annually, including procedures for ablation and the placement of pacing leads. As a result, we believe that the Stereotaxis System can provide substantial clinical benefits compared to manual interventional methods in more than 500,000 worldwide annual procedures.

The Stereotaxis System is designed to address the needs of patients, hospitals, physicians, and third-party payors on a cost-effective basis by:

- meeting patient demands for less invasive procedures, while improving patient safety and outcomes;
- enabling new procedures in interventional cardiology and electrophysiology that currently cannot be performed, or are extremely difficult to perform, with manual methods;
- enhancing the productivity of existing complex interventional procedures, by both shortening procedure times and making them more predictable, thereby improving cath lab scheduling efficiency and lowering total costs;
- decreasing the number of disposable interventional devices used per procedure, thereby potentially lowering provider costs;
- providing ease of use and lowering physician skill barriers for complex cardiology procedures; and
- decreasing exposure to x-ray fluoroscopy fields for patients and physicians and reducing the use of contrast dye injections, both of which are potentially harmful.

We have alliances with each of Siemens AG Medical Solutions, Philips Medical Systems and Biosense Webster, a subsidiary of Johnson & Johnson. Through these alliances, we are integrating our Stereotaxis System with Siemens' and Philips' market leading digital imaging and J&J's 3D catheter location sensing technology, and developing compatible disposable interventional devices, in order to continue to introduce new solutions to the cath lab. Together, Siemens and Philips have a combined installed base of more than 2,200 cardiology cath labs in the U.S., while J&J has the leading market position in 3D catheter location sensing technology, an important technology in complex electrophysiology ablation procedures. The Siemens and Philips alliances provide for coordination of our sales and marketing with that of our partners to facilitate co-placement of integrated systems. In addition, Siemens and Philips have agreed to provide worldwide service for our integrated systems. In connection with these alliances, Siemens invested \$10 million and J&J invested \$9.5 million in our equity in private placements prior to our initial public offering, and Philips agreed to make payments of up to \$7.5 million relating to the integration of its x-ray fluoroscopy system with the Stereotaxis System.

The core elements of our Stereotaxis System are protected by an extensive patent portfolio, as well as substantial know-how and trade secrets.

## **Background**

Traditionally, cardiac procedures have been performed via open chest heart bypass surgery. This procedure is very invasive, requiring cutting open the rib cage and spreading it apart in order to gain access to the heart. This

enables the physician to directly view the patient's heart during the procedure and to operate manually. Additionally, the patient is typically placed on a heart lung bypass device. While generally very effective, the procedure is highly traumatic for the patient, and usually requires a long hospital stay, followed by a significant period of convalescence. Conventional cardiac surgery is also expensive, with a procedure cost that can range as high as \$100,000.

Minimally invasive surgical procedures for cardiology were devised to mitigate many of the drawbacks of bypass surgery while maintaining essential elements of visualization and instrument control. These procedures utilize an endoscope for visualization, which is inserted through an incision in the patient's body. While these minimally invasive surgical techniques have been used for a number of cardiac procedures, in most instances they have not been as effective as conventional cardiac surgery. As a result, bypass surgery, despite its drawbacks, has remained the predominant method for cardiac surgical procedures.

Interventional cardiology represents the next, and most recent, step in the evolution of less invasive cardiac procedures. These procedures are performed in the cath lab, where real-time x-ray imaging, often enhanced by the injection of contrast dye, provides visualization enabling physicians to insert and navigate guidewires, catheters and stent delivery devices into the vasculature or open chambers of the heart to deliver therapy. Instrument control in typical interventional cardiology procedures for the treatment of coronary artery disease requires the physician to manually manipulate the external end of a long, slender guidewire in order to indirectly control and position the working tip of the instrument. This requires significant skill and, depending upon the type and location of the lesion being treated, can be very difficult and time consuming. The guidewire is typically used for navigation to the treatment site, after which a catheter or stent delivery device is threaded over the guidewire to perform the necessary treatment. Guidewires are also typically used to place pacemaker leads used in cardiac resynchronization therapy for the treatment of congestive heart failure. In electrophysiology mapping and ablation procedures, physicians use specialized catheters that are manually navigated using a system of mechanical control cables to map the patient's heart, and then to ablate the heart tissue to eliminate arrhythmias. This also requires significant skill, and, depending on the type and location of the arrhythmia, can be very difficult and time consuming to perform.

Interventional cardiology and electrophysiology procedures have proven to be very effective at treating coronary artery disease and arrhythmias at sites accessible through the vasculature without the patient trauma, complications, recovery times and cost generally associated with open surgery. With the advent of drug-eluting stents, the number of potential patients who could benefit from interventional cardiology procedures has grown. However, major challenges associated with manual approaches to interventional cardiology and electrophysiology persist. In interventional cardiology, these challenges include difficulty in navigating the disposable interventional device through tortuous vasculature and crossing certain types of complex lesions to deliver drug-eluting stents to effect treatment. As a result, numerous patients who could be candidates for an interventional approach continue to be referred to bypass surgery. In electrophysiology, these challenges include precisely navigating the tip of the mapping and ablation catheter to the treatment site on the heart wall and maintaining tissue contact throughout the cardiac cycle to effect treatment, and, for atrial fibrillation, performing complex ablations within the left atrium of the heart. As a result, large numbers of patients are referred to palliative drug therapy that can have harmful side effects.

We believe the Stereotaxis System represents a revolutionary step in the trend toward highly effective, but less invasive, cardiac procedures. As the first technology to permit direct, computerized control of the working tip of a disposable interventional device, the Stereotaxis System enables physicians to perform cardiac procedures interventionally that historically would have been very difficult or impossible to perform in this way and significantly improves the efficiency of existing complex procedures in the cath lab.

## **The Growing Importance of the Cath Lab**

We believe that the cath lab's position as a hospital profit center, coupled with the growth of interventional procedures, has made it possible for decision-makers to justify large expenditures on capital equipment for use within the cath lab. As a result, hospitals with cath labs have tended to be early adopters of new technologies.

There has also been a major trend toward using digital rather than analog instrument systems in the cath lab, resulting in the rapid replacement of analog electrophysiology recording systems with digital recording systems and the current rapid replacement of analog x-ray fluoroscopy systems with digital x-ray fluoroscopy systems. Additionally, new sources of diagnostic information such as 3D catheter location sensing technology and catheter-based ultrasound are being introduced to the cath lab. As a result, interventional procedures require physicians to analyze large quantities of information from many disparate imaging and information sources. We believe that the Stereotaxis System provides an important link in completing the digital transformation of the cath lab, because it is the only system that integrates the visualization and information systems in the cath lab with digital control of the working tip of catheters, guidewires and stent delivery devices. Furthermore, because the Stereotaxis System brings precise remote digital instrument control and programmability to the cath lab, we believe it can displace conventional manual control of disposable interventional devices for complex cardiology procedures in the same way that digital control, or "fly by wire" technology, replaced mechanical control of the modern jet airplane.

Interventional techniques are routinely used in interventional cardiology to treat partially occluded coronary arteries with balloon angioplasty and to place coronary stents, and in electrophysiology to treat certain types of arrhythmias. In the U.S. there are more than 1.1 million interventional cardiology procedures performed for the treatment of coronary artery disease each year, which represents approximately 60% of the total number of such procedures performed on a worldwide basis. Each year in the U.S., there are also more than 500,000 electrophysiology procedures for treatment of arrhythmia, including more than 340,000 electrophysiology mapping procedures and more than 160,000 ablation procedures, which represents approximately 65% of the total number of electrophysiology procedures performed on a worldwide basis. Interventional treatments are also emerging for atrial fibrillation and congestive heart failure, and industry estimates indicate that the U.S. procedure base for these diseases has the potential to grow rapidly if more effective interventional treatments are available.

There are approximately 3,700 cardiology cath labs in the U.S. installed at approximately 1,900 hospitals. Based on procedure volume, we estimate that there are over 2,000 cardiology cath labs located throughout the rest of the world. We estimate that there are more than 750 new and replacement cardiology cath labs installed each year worldwide.

## **Current Challenges in the Cath Lab**

Although great strides have been made in applying manual interventional techniques, significant challenges remain that reduce cath lab productivity and limit both the number of complex procedures and the types of diseases that can be treated. These challenges primarily involve the limitations of manual instrument control and the lack of integration of the information systems used by physicians in the cath lab. As a result, many complex procedures in interventional cardiology are referred to highly invasive bypass surgery and many complex cases in electrophysiology are treated with palliative drug therapy.

## **Limitations of Instrument Control**

Navigation in the blood vessels and the chambers of the heart can be difficult because the path that a disposable interventional device must follow to arrive at the treatment site and deliver therapy can be complex and tortuous. Physicians using manual methods often utilize a range of different catheters and guidewires in succession in an attempt to find the right device or devices for the procedure being performed.

Manually controlled catheters, guidewires and stent delivery devices, even in the hands of the most skilled specialist, have inherent instrument control limitations. In traditional interventional procedures, the device is manually manipulated by the physician who twists and pushes the external end of the instrument in an iterative process to thread the instrument through the blood vessels to the treatment site. Manual control of the working tip becomes increasingly difficult as more turns are required to navigate the instrument to the treatment site, as the blood vessels to be navigated become smaller and less accessible or more blocked, and as greater precision is required to carry out therapy at the treatment site.

### **Lack of Integration of Information Systems**

While sophisticated imaging, mapping and location-sensing systems have provided visualization for interventional procedures and allowed interventional physicians to treat more complex conditions, the substantial lack of integration of these information systems requires the physician to mentally integrate and process large quantities of information from different sources in real time during an interventional procedure. For example, a physician ablating heart tissue to eliminate an arrhythmia will often be required to mentally integrate information from a number of sources, including:

- real-time x-ray fluoroscopy images;
- a real-time location-sensing system providing the 3D location of the catheter tip;
- a pre-operative map of the electrical activity or anatomy of the patient's heart;
- real-time recording of electrical activity of the heart; and
- temperature feedback from an ablation catheter.

Each of these systems displays data differently, requiring physicians to continuously reorient themselves to the different formats and displays as they shift their focus from one data source to the next while at the same time manually controlling the interventional instrument.

### **The Stereotaxis Value Proposition**

The Stereotaxis System addresses the current challenges in the cath lab by providing precise computerized control of the working tip of the interventional instrument and by integrating this control with the visualization and information systems used during interventional cardiology and electrophysiology procedures, on a cost justified basis. We believe that the Stereotaxis System is the only technology to be commercialized that allows remote, computerized control of disposable interventional devices directly at their working tip.

We believe that the Stereotaxis System will:

- Expand the market by enabling new treatments for major diseases and permitting the treatment of more complex existing cases. Treatment of a number of major diseases, including chronic totally occluded coronary arteries and atrial fibrillation, is highly problematic using conventional catheter-based techniques. Additionally, many patients with multi-vessel disease and certain complex arrhythmias are often referred to other therapies because of the difficulty in controlling the working tip of disposable interventional devices. As a result, these patients are typically referred to more invasive surgeries or largely ineffective drug therapy. Because the Stereotaxis System provides precise, computerized control of the working tip of disposable interventional devices, we believe that it will potentially enable chronic totally occluded coronary arteries and atrial fibrillation to be treated interventionally on a much broader scale than today, and may permit physicians to predictably treat complex cases involving partially occluded coronary arteries and arrhythmias.
- Improve outcomes by optimizing therapy. Difficulty in controlling the working tip of disposable interventional devices leads to sub-optimal results in many procedures. Precise instrument control is necessary for



treating a number of cardiac conditions, including arrhythmias, where precise placement of an ablation catheter against a beating inner heart wall is necessary, and congestive heart failure, where precise navigation within the coronary venous system for optimal placement of pacemaker leads is required. Precise and correct navigation and placement of expensive drug-eluting stents also have a significant impact on procedure costs and outcomes. We believe the Stereotaxis System can enhance procedure results by improving navigation of disposable interventional devices to treatment sites, and by effecting more precise treatments once these sites are reached.

- Enhance hospital efficiency by reducing and standardizing procedure times, disposables utilization and staffing needs. Interventional procedure times currently range from several minutes to many hours as physicians often engage in repetitive, “trial and error” maneuvers due to difficulties with manually controlling the working tip of disposable interventional devices. By reducing both navigation time and the time needed to carry out therapy at the target site, we believe that the Stereotaxis System can reduce complex interventional procedure times compared to manual procedures. We believe the Stereotaxis System can also reduce the variability in procedure times compared to manual methods. Greater standardization of procedure times allows for more efficient cath lab scheduling. We also believe that additional cost savings from the Stereotaxis System result from decreased use of multiple catheters and guidewires in procedures compared with manual methods and also from decreased staff requirements during procedures, which further enhances the rate of return to hospitals.
- Improve the efficacy of complex cardiology procedures by enhancing physician skill levels. Training required for physicians to carry out manual interventional procedures typically takes years, over and above the training required to become a specialist in cardiology, leading to a shortage of interventional physicians for more complex procedures. The Stereotaxis System can allow procedures that previously required the highest levels of manual dexterity and skill to be performed effectively by a broader range of interventionalists, with more standardized outcomes. In addition, interventional physicians can be trained to use the Stereotaxis System in a relatively short period of time. The Stereotaxis System can also be programmed to carry out sequences of complex navigation automatically.
- Improve patient and physician safety by reducing procedure times and minimizing x-ray exposure and the use of contrast dye injections. During conventional catheter-based procedures, both the physician, who stands by the patient table to manually control the catheter, and the patient are exposed to the potentially harmful x-ray fluoroscopy field. This exposure can be minimized by reducing procedure times. Reducing procedure times is also beneficial to the patient because there is a direct correlation between complication rates and procedure length. Shorter procedure times and improved navigation result in reduced use of contrast dye injections which are potentially harmful to the patient. The Stereotaxis System can further improve physician safety by enabling them to conduct procedures remotely from an adjacent control room, which reduces their exposure to harmful radiation and helps alleviate orthopedic problems that often result from wearing heavy lead vests to shield them from x-ray exposure during procedures.

## **Business Strategy**

Our goal is to establish the Stereotaxis System as the standard of care for complex interventional procedures in cardiology by bringing magnetic instrument control into standard interventional clinical practice. The key elements of our strategy for achieving this goal are to:

- Leverage the efficiency and productivity improvements enabled by our system to present a compelling economic justification to hospitals. We believe our system enhances the rate of return to hospitals by optimizing cath lab economics, reducing procedure times, disposable interventional device usage and staffing requirements during procedures. This allows us to present a compelling economic justification to hospitals for the purchase of our systems.

- Integrate our system with our key strategic partners' products and leverage our partnerships to assist in further development, commercialization, sales and service of our products. We are integrating our system with Siemens' and Philips' widely used imaging equipment and J&J's advanced 3D catheter location sensing technology to provide seamless integration of instrument control and visualization and a toolkit of disposable interventional devices that we believe will enable new therapeutic solutions in the cath lab. We have also entered into a manufacturing and supply agreement with Lake Region Manufacturing, one of the world's leading manufacturers of guidewires for use in interventional medicine, to provide high volume capability for guidewires. We intend to continue leveraging the sales, distribution, service and maintenance expertise of our strategic partners to facilitate co-placement of integrated systems and disposable interventional devices and to support and maintain our equipment at installed sites. See "Business—Collaborations" for a further description of our strategic partnerships. We intend to selectively expand the number of co-marketing agreements that we have with major companies in the cath lab market in order to augment the effectiveness of our direct sales force and distribution network, and to add distributors to extend coverage to key areas outside the U.S. We also intend to selectively enter into additional licensing, development and manufacturing partnerships with major disposables companies in order to expand the number of magnetically controlled disposable interventional devices that can be used with the Stereotaxis System. We will continue to outsource major components and sub-assemblies of our equipment to maximize manufacturing flexibility and lower fixed costs, while maintaining quality control by completing final system assembly and inspection in-house.
- Provide an essential digital link in the cath lab between imaging systems and instrument control. We intend to maintain an open architecture approach to connectivity in the cath lab in order to encourage the major imaging companies to consider Stereotaxis an essential ingredient for digital integration and automation in the cath lab. We believe that integrating our system with key imaging and visualization technologies using an open architecture approach is a key element in establishing our system as the standard of care for complex interventional procedures.
- Expand clinical applications for, and utilization of, our technology. We intend to pursue clinical research with leading interventional cardiologists and electrophysiologists in order to further develop and expand the range of clinical applications for magnetic instrument control in the field of cardiology. We also intend to provide comprehensive training and educational programs for physicians regarding the use and benefits of our system in order to increase the overall utilization of our technology. We believe that we can build on our experience in the cardiology field to expand the scope of our technology to other major clinical areas where there are potential unmet needs for better device navigation and control.
- Capitalize on our technology leadership to enhance our competitive position. We intend to enhance and maintain our technology leadership with focused research and development. We also intend to build on our "first mover" advantage to establish Stereotaxis as the preferred approach for cath lab automation, by providing continuous improvement of our technology and user-friendly software. We will continue to protect our intellectual property through additions to our already significant patent portfolio in order to cover the key aspects of our technology, including new magnet designs, catheter and guidewire designs, remote control systems, systems integration and automation and software development.

## **Overview of the Stereotaxis System**

Our proprietary Stereotaxis System provides the physician with precise remote digital instrument control through user friendly "point and click" and/or joystick-operated technology, which can be operated either from beside the patient table, as in traditional interventional procedures, or from a room adjacent to the patient and outside the x-ray fluoroscopy field. The NIOBE cardiology magnet system navigates disposable interventional devices to the treatment site through complex paths in the blood vessels and chambers of the heart to carry out treatment using computer controlled, externally applied magnetic fields to directly govern the motion of the working tip of these devices, each of which has a magnetically sensitive tip that predictably responds to magnetic fields generated by our system. Because the working tip of the disposable interventional device is directly controlled by

these external magnetic fields, the physician has the same degree of control regardless of the number or type of turns, or the distance traveled, by the working tip to arrive at its position in the blood vessels or chambers of the heart, which results in highly precise digital control of the working tip of the disposable interventional device while still giving the physician the option to manually advance the catheter.

Through our alliances with Siemens, Philips and J&J, this precise digital instrument control has been integrated with the visualization and information systems used during interventional cardiology and electrophysiology procedures in order to provide the physician with a fully-integrated and automated information and instrument control system. We have integrated our Stereotaxis System with Siemens' digital x-ray fluoroscopy system, and we have completed the initial integration with Philips' digital x-ray fluoroscopy system. In addition, we are integrating the Stereotaxis System with J&J's 3D catheter location sensing technology, to provide accurate real-time information as to the 3D location of the working tip of the instrument, and with J&J's ablation tip technology. We believe that the combination of these features will provide more effective instrument control and therapy delivery.

The components of the Stereotaxis System are identified and described below:

## **Systems**

**NIOBE Cardiology Magnet System.** Our NIOBE cardiology magnet system utilizes two permanent magnets mounted on articulating or pivoting arms that are enclosed within a stationary housing, with one magnet on either side of the patient table, inside the cath lab. These magnets generate magnetic navigation fields that are less than 10% of the strength of fields typically generated by MRI equipment and therefore require significantly less shielding, and cause significantly less interference, than MRI equipment.

**NAVIGANT Advanced User Interface.** The NAVIGANT advanced user interface is an integrated information and control center that consolidates the key information sources used by interventional cardiologists and electrophysiologists and allows these physicians to provide instrument control directions to precisely govern the motion of the working tip of disposable interventional devices.

The NAVIGANT advanced user interface consists of:

- configurable display screens located both next to the patient table inside the cath lab and in the adjacent control room, outside the x-ray fluoroscopy field, that provide advanced visualization and information integration to the physician;
- sophisticated embedded device software and system control algorithms that are integrated with our disposable interventional devices to facilitate ease of use and improved navigation of these devices;
- computer joystick or mouse control which the physician uses to direct the motion of the working tip of the disposable interventional device, either from inside the cath lab or from the adjacent control room; and
- a software package designed for interventional cardiology or electrophysiology, or both, as well as optional application software tailored for specific clinical procedures.

**CARDIODRIVE Automated Catheter Advancer.** Where the physician is conducting the procedure from the adjacent control room, the CARDIODRIVE automated catheter advancer is used to advance and retract the catheter in the patient's heart while the NIOBE magnets precisely steer the working tip of the device.

We have received the FDA clearance and the CE Mark necessary for us to market the NIOBE cardiology magnet system, the NAVIGANT advanced user interface and the CARDIODRIVE automated catheter advancer in the U.S. and Europe.

## **Disposables and Other Accessories**

Our system is designed to use a toolkit of proprietary disposable interventional devices. The toolkit currently consists of:

- our suite of CRONUS® coronary guidewires suitable for use in interventional cardiology procedures for the introduction and placement of over-the-wire therapeutic devices, such as biventricular pacing leads used in cardiac resynchronization therapy for treating congestive heart failure;
- our TANGENT® electrophysiology mapping catheter used to locate aberrant electrical signals in the heart;
- our HELIOS® electrophysiology ablation catheter used for certain arrhythmia treatments; and
- the Celcius ablation and Navistar mapping and catheters co-developed with J&J, as described below.

We have received the FDA clearance and the CE Mark necessary for us to market our suite of CRONUS coronary guidewires and our electrophysiology mapping catheter in the U.S. and Europe. In addition, we have received the CE Mark for our HELIOS electrophysiology ablation catheter and, in the U.S., we have completed clinical trials in 2004 and expect to subsequently file for a PMA.

Through our alliance with J&J, we are co-developing a range of ablation catheters that can be navigated with our system, with and without J&J's 3D catheter location sensing technology. We are also developing disposable interventional devices for other applications. In addition, we have developed plastic software keys, or smart chips, that allow our system to recognize specific disposable interventional devices in order to prevent unauthorized use of our system.

In March 2005, we announced the first commercial use of our Stereotaxis system with the Celcius™ RMT ablation catheter, the Navistar™ RMT mapping and ablation catheter and the CARTO™ RMT mapping and ablation system in Europe. These products, which had recently received CE Marking authorization in Europe and other countries that recognize the CE Mark, are the first products to be commercialized pursuant to our strategic alliance with J&J. We expect that approvals in the United States will follow in 2005 and that Biosense Webster will continue to develop other magnetically enabled catheters into 2006.

We believe that we can adapt most disposable interventional devices for use with our system by using our proprietary technology to add an inexpensive micro-magnet at their working tip. This micro-magnet is activated by an external magnetic field, which allows interventional devices with tip dimensions as small as 14 thousandths (0.014) of an inch to be oriented and positioned in a predictable and controllable fashion. We believe this approach to bringing digital control to disposable interventional devices using embedded magnets can simplify the overall design of these devices and reduce their manufacturing costs because mechanical controls are no longer required.

## **Clinical Applications**

We have initially focused our clinical and commercial efforts on applications of the Stereotaxis System in complex interventional cardiology procedures for the treatment of coronary artery disease, and in electrophysiology procedures for the treatment of arrhythmias. Our system potentially has broad applicability in other areas, such as interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine, and our patent portfolio has been structured to permit expansion into these areas.

## **Interventional Cardiology**

Nearly half a million people die annually from coronary artery disease, a condition in which the formation of plaque in the coronary arteries obstructs the supply of blood to the heart, making this the leading cause of death in the

U.S. Despite various attempts to reduce risk factors, each year over one million patients undergo interventional procedures in an attempt to open blocked vessels and another half a million patients undergo open heart surgery to bypass blocked coronary arteries.

Blockages within a coronary artery, often called lesions, are categorized by degree of obstruction as partial occlusions, non-chronic total occlusions and chronic total occlusions. Lesions are also categorized by the degree of difficulty with which they can be opened as simple or complex. If the blockage is in an easy to reach location, it can typically be treated by pushing a guidewire through the portion of the vessel that is blocked with plaque, expanding a small balloon to compress the plaque against the artery walls in order to open the artery, and then finally deploying a stent, which is a small metal scaffold, to help keep the artery open. If a blockage is located within tortuous vasculature, however, the physician must navigate the guidewire through a series of sharp turns, making the blockage very difficult to reach. Even if such lesions are reached, delivering a balloon or stent to the treatment site through tortuous anatomy can be difficult. In addition, complex lesions, such as chronic total occlusions, longer lesions, and lesions located within smaller diameter vessels, are often very difficult or time consuming to open with manual interventional techniques.

Physicians are currently performing approximately 1.8 million interventional cardiology procedures world-wide each year, and we estimate that approximately 15%, or 270,000, of these procedures are complex and therefore require longer procedure times and may have sub-optimal outcomes. We believe that our system can substantially benefit this subset of complex interventional cardiology procedures, including procedures involving:

- Complex partial occlusions, complex non-chronic total occlusions and chronic total occlusions. Treatment of these complex lesions is generally more problematic due to the difficulty in steering and pushing a guidewire through them. Because our system provides precise computerized control of the working tip of a guidewire, it can enable physicians to more easily locate small openings in, and to advance a guidewire across, these lesions. Also, our magnetically steerable microcatheter can help steer a variety of conventional wire products, some of which are designed to cross complex lesions, but which otherwise lack the controlled steering needed to avoid perforating the vessel wall. The ability to cross complex lesions such as chronic total occlusions has grown increasingly important due to the effectiveness of drug eluting stents in treating these lesions. Since approximately one-fifth of patients referred to bypass surgery have chronic total occlusions, we believe a significant number of patients could be treated interventionally instead of surgically if more of these lesions could be opened for stenting.
- Tortuous Anatomy.  
We estimate that between 10 and 15% of all interventional procedures require physicians to navigate a disposable interventional device through a series of sharp turns in the patient's vasculature. Navigating through tortuous anatomy using manual interventional techniques can be very time consuming and physicians often cannot reach the lesion or manipulate the balloon or stent across the lesion once it is reached. Because our system allows the working tip of disposable interventional devices to be precisely oriented regardless of the number of turns that have occurred, our technology allows physicians to more effectively navigate these devices through complex vasculature and deliver balloons and stents to treatment sites for therapy.
- Stent placement.  
The likelihood of restenosis, or re-blockage of cleared arteries, is greatly increased in multi-vessel diseased patients whose blockages are typically more diffusely distributed throughout longer lengths of the vessel. As a result, these patients are often referred to invasive bypass surgery. We expect that drug-eluting stents, which dramatically reduce the likelihood of restenosis, will enable patients with more complex lesions to be treated interventionally rather than with bypass surgery. In order to treat this new group of patients, however, physicians will need to place stents in more challenging or remote locations. By using externally applied magnetic fields to precisely direct a stent through a patient's vasculature, we believe that our system allows these devices to be more easily navigated to these difficult to reach treatment sites.

- **Small Vessels.**

Based on our interpretation of various medical studies, we have determined that diabetic patients usually comprise about 20 to 30% of U.S. hospital's interventional procedure volume. These patients generally have smaller vessels, which often contain longer lesions with more diffusely distributed blockages, as well as tortuous anatomy, making guidewire navigation and stent delivery extremely difficult. We believe that these patients can benefit significantly from the improved disposable interventional device navigation enabled by our system.

## **Electrophysiology**

The rhythmic beating of the heart results from the transmission of electrical impulses through the heart. When these electrical impulses are mis-timed or uncoordinated, the heart fails to function properly, resulting in complications that can range from fatigue to stroke or death. Over four million people in the U.S. currently suffer from the resulting abnormal heart rhythms, which are known as arrhythmias.

Drug therapies for arrhythmias often fail to adequately control the arrhythmia and may have significant side effects. Consequently, physicians have increasingly sought more permanent, non-pharmacological, solutions for arrhythmias. The most common interventional treatment for arrhythmias, and in particular tachyarrhythmias, where the patient's heart rate is too high or irregular, is an ablation procedure in which the diseased tissue giving rise to the arrhythmia is isolated or destroyed. Prior to performing an electrophysiology ablation, a physician typically performs a diagnostic procedure in which the electrical signal patterns of the heart wall are "mapped" to identify the heart tissue generating the aberrant electrical signals. Following the mapping procedure, the physician may then use an ablation catheter to disable the aberrant signal or signal path, restoring the heart to its normal rhythm. In cases where an ablation is anticipated, physicians will choose an ablation catheter and perform both the mapping and ablation with the same catheter.

Based on an analysis of industry data, we have determined that physicians are currently performing approximately 800,000 electrophysiology procedures worldwide each year, including approximately 500,000 electrophysiological mapping procedures, approximately 240,000 ablation procedures and approximately 60,000 other procedures such as treatment of atrial fibrillation and congestive heart failure. We believe the Stereotaxis System is particularly well-suited for those electrophysiology procedures which are time consuming or which can only be performed by highly experienced physicians, which we estimate to be approximately 30% of all electrophysiology procedures performed worldwide each year. We estimate that the number of these complex procedures is growing at a rate of approximately 12% per year. These procedures include:

- **Lengthy Ablations.**

For the more routine but lengthy mapping and ablation procedures, our system offers the unique benefit of automating the procedure and directing catheter movement from the control room, saving the physician time and helping to avoid unnecessary exposure to high doses of radiation.

- **Atrial Fibrillation.**

A common cause of sustained abnormal heart rhythm, atrial fibrillation, is a particular type of arrhythmia characterized by rapid, disorganized contractions of the heart's upper chambers, the atria, which lead to ineffective heart pumping and blood flow and can be a major risk factor for stroke. The majority of potential patients cannot benefit from manual catheter-based procedures for atrial fibrillation because they are extremely complex and are performed by only the most highly skilled electrophysiologists. They also typically have much longer procedure times than conventional ablation cases and success rates that are only in the 50% to 80% range. We believe that our system can allow these procedures to be performed by a broader range of electrophysiologists and, by automating some of the more complex ablation routines, can standardize and reduce procedure times and significantly improve outcomes.

- **Bi-Ventricular Pacing.**

Congestive heart failure is a potentially fatal condition in which the heart muscle is damaged to the point that it is unable to provide adequate blood flow rate through the body. A new therapy, dual chamber cardiac resynchronization therapy, or bi-ventricular pacing, has shown promise in the treatment of a certain type of congestive heart failure in which the left and right sides of the left ventricle do not contract at the same time. The procedure used to carry out this therapy involves the placement of a pacemaker lead into the coronary venous system of the heart. Interventional treatment of this patient population is growing rapidly but the placement of the venous pacing lead with manual interventional technologies is highly challenging and time consuming, and less than optimal lead placement can contribute to poor outcomes. The unpredictability of procedure times also makes efficient cath lab scheduling very difficult in these cases. We estimate that approximately 50,000 biventricular pacing leads are currently placed per year worldwide. Industry estimates indicate, however, that if there were a more effective method of placing these pacing leads, more than 700,000 congestive heart failure patients per year in the U.S. would be eligible for the procedure.

We believe that our system can address the current challenges in electrophysiology by permitting the physician to remotely navigate disposable interventional devices from a control room outside the x-ray field. Our system also allows for more predictable and efficient navigation of these devices to the treatment site, including the left atrium for atrial fibrillation procedures, and enables appropriate contact force to be maintained to effect ablations on the wall of the beating heart. We also believe that our system will significantly lower the skill barriers required for physicians to perform complex electrophysiology procedures and, additionally, improve cath lab efficiency and reduce disposable interventional device utilization.

### **Interventional Neuroradiology, Neurosurgery and Other Interventional Applications**

Physicians used a predecessor to our NIOBE system to conduct a number of procedures for the treatment of brain aneurysms, a condition in which a portion of a blood vessel wall balloons and which can result in debilitating or fatal hemorrhagic strokes. Traditional treatment for brain aneurysms involves highly invasive open brain surgery. Interventional procedures have evolved for filling the aneurysm with platinum micro-coils delivered to the site in order to reduce blood flow within the aneurysm. We believe that the Stereotaxis System has the potential to be adapted for use in the interventional treatment of brain aneurysms, by enabling physicians to reach a broader range of aneurysm targets, and by making procedure times for these cases more predictable.

The Stereotaxis System also has a range of potential applications in minimally invasive neurosurgery, including biopsies and the treatment of tumors, treatment of vascular malformations and, when deliverables are commercialized by third parties, delivery of pharmacological compounds and deep brain stimulators. We have successfully conducted what we believe to be the first human surgical procedures ever conducted using computerized control in our neurosurgery program by navigating complex pathways through brain tissue to multiple target sites. The Stereotaxis System also has applicability in the respiratory, gastro-intestinal and genito-urinary systems, for diagnosis and treatment of diseases affecting the lungs, prostate, kidneys, colon and small intestine. We do not anticipate any significant revenue from these programs in the near term.

### **Collaborations**

We have entered into collaborations with four technology leaders in the global cath lab market, Siemens, Philips, J&J and Lake Region Manufacturing, that we believe will aid us in commercializing our Stereotaxis System. We believe our two imaging partners, Siemens and Philips, have a combined installed base of more than 2,200 cardiology cath labs in the U.S.

We believe that these collaboration arrangements are favorable to Stereotaxis because they:

- provide for the integration of our system with market leading digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices;
- allow us to leverage the sales, distribution, service and maintenance expertise of our strategic partners; and
- enable operational flexibility by not requiring us to provide any of our strategic partners with a right of first refusal in the event that another party wants to acquire us or with board representation where a strategic partner has made a debt or equity investment in us.

## **Imaging Partners**

*Siemens Alliance.* In June 2001, we entered into an alliance with Siemens, a global leader in cath lab equipment sales, including x-ray fluoroscopy systems. Under this alliance, we successfully integrated our Stereotaxis System with Siemens' digital fluoroscopy system to provide advanced cath lab visualization and instrument control through user-friendly computerized interfaces. We also coordinate our sales efforts with Siemens to co-place integrated systems at leading hospital sites in the U.S. and Europe. Under this alliance and under a separate services agreement, Siemens provides site planning, project management, equipment maintenance and support services for our products directly to our customers. To date, all of our systems placed for clinical use have been integrated with Siemens' digital fluoroscopy systems.

In May 2003, we entered into an expanded alliance with Siemens, under which we are collaborating to produce what we believe will be market leading technology to provide physicians with real-time 3D visualization of a patient's anatomy during a procedure by integrating pre-operative MRI and CT data with x-ray fluoroscopic data. We also agreed to integrate our instrument control technology with Siemens' imaging technology in order to develop new solutions in cardiology and, potentially, in interventional radiology. Where Siemens' proprietary technology is incorporated into products being co-developed under this expanded alliance, there are restrictions on our ability to use that technology to sell Stereotaxis Systems integrated with other third party x-ray imaging systems. These restrictions expire no later than December 31, 2005. We have also entered into a separate development agreement for the Japanese market under which Siemens will coordinate regulatory approval and distribute, install and service our Stereotaxis Systems, whether integrated with the x-ray system of Siemens, or other third parties, in Japan. We have also entered into a software distribution agreement with Siemens under which we have the right to sublicense Siemens' 3D pre-operative image navigation software as part of our NAVIGANT advanced user interface.

Concurrently with entering into the expanded alliance, Siemens invested \$10 million in our Series E preferred stock in 2003. Siemens also held a \$2 million note convertible into Stereotaxis common stock, which was issued by us in connection with the purchase of certain of Siemens' intellectual property in August 2003. Both the Series E preferred stock and this note were converted into our common stock in connection with our IPO in August 2004. See "Certain Relationships and Related Party Transactions".

*Philips Alliance.* In October 2003, we entered into an alliance with Philips, another recognized global leader in cath lab sales, pursuant to which we agreed to integrate our Stereotaxis System with Philips' digital x-ray fluoroscopy system to achieve seamless integration of our instrument control technology and Philips' digital x-ray imaging on a user friendly basis. We also agreed with Philips to identify areas of concentration for bringing new solutions to integration of information sources and instrument control in the cath lab in cardiology and neurology. Under this alliance, we will coordinate our sales efforts with Philips in order to co-place our integrated systems. Philips also agreed to pay our engineering and other costs of the integration and related research and development work, and agreed to purchase a maximum of three promotional integrated Stereotaxis Systems from us for installation at agreed upon "centers of excellence." Additionally, Philips has agreed to pay various co-placement fees to Stereotaxis for each of the first 70 systems integrated with Philips that are shipped commercially. The total amount



that we are entitled to receive from Philips under this agreement for research and development costs, co-placement fees and the purchase of our promotional integrated Stereotaxis Systems is capped at \$7.5 million.

### **Disposables Partners**

*J&J Alliance.* We entered into an alliance with J&J in May 2002 pursuant to which we agreed to integrate J&J's advanced Biosense 3D catheter location sensing technology, which we believe has the leading market position in this important field of visualization for electrophysiology procedures, with our instrument control system, and to jointly develop associated location sensing electrophysiology mapping and ablation catheters that are navigable with the Stereotaxis System. We believe that these integrated products will provide physicians with the elements required for effective complex electrophysiology procedures: highly accurate information as to the exact location of the catheter in the body and highly precise control over the working tip of the catheter. We also agreed to coordinate our sales force efforts with J&J in order to place J&J Biosense CARTO Systems and our Stereotaxis Systems that, together with the co-developed catheters, will comprise the full integration of our instrument control and 3D location sensing technologies in the cath lab. We expanded this alliance in November 2003 to include the parallel integration of our instrument control technology with J&J's full line of non-location sensing mapping and ablation catheters that are relevant to our targeted applications in electrophysiology.

The co-developed catheters will be manufactured and distributed by J&J, and each of the parties agreed to contribute to the resources required for their development. We are entitled to royalty payments from J&J, payable quarterly based on a profit formula for sales of the co-developed catheters, and our revenue share increases under certain circumstances. Under this alliance, we agreed to certain restrictions on our ability to co-develop and distribute catheters competitive with those we are developing with J&J and granted J&J certain notice and discussion rights for product development activities we undertake relating to localization and magnetically enabling interventional disposable devices in cardiology fields outside of electrophysiology and mapping. In connection with our expanded alliance, J&J also invested \$9.5 million in our Series E-1 preferred stock in 2003. This preferred stock was converted into our common stock in connection with our IPO in August 2004.

Either party may terminate this alliance in certain specified "change of control" situations, although the termination would not be effective until one year after the change of control and then would be subject to a wind-down period during which J&J would continue to supply co-developed catheters to us or to our customers for three years (or, for non-location sensing mapping and ablation catheters, until our first sale of a competitive product after a change of control, if earlier than three years). If we terminate the agreement under this provision, we must pay a termination fee to J&J equal to 5% of the total equity value of Stereotaxis in the change of control transaction, up to a maximum of \$10 million. We also agreed to notify J&J if we reasonably consider that we are engaged in substantive discussions in respect of the sale of the company or substantially all of our assets. See "Certain Relationships and Related Party Transactions".

*Lake Region.* We entered into an agreement with Lake Region Manufacturing, Inc., one of the world's leading manufacturers of guidewires for the development and production of magnetically enabled guidewires in January 2005. The agreement provides Stereotaxis with the wherewithal to increase both the availability and the technological sophistication of its guidewires to better meet customer needs.

### **Research and Development**

Our research and development team consists of 49 people focused on system and disposable interventional device development. We have assembled an experienced group of engineers and physicists with recognized expertise in magnetics, software, control algorithms, systems integration and disposable interventional device modeling and design.

Our research and development efforts are focused in three major areas:

- continuing to enhance our existing system through ongoing product and software development;
- designing new proprietary disposable interventional devices for use with our system; and
- developing next generation versions of our system.

Our research and development team collaborates with our strategic partners, Siemens, Philips, and J&J, to integrate our Stereotaxis System's open architecture platform with key imaging, location sensing and information systems in the cath lab. We have also collaborated with a number of highly regarded interventional physicians in key clinical areas and have entered into agreements with a number of universities and research institutions, which serve to increase our access to world class physicians and scientists and to expand our name recognition in the medical community.

We have historically spent a significant portion of our capital resources on research and development, incurring \$18.4 million in 2004, \$13.9 million in 2003 and \$14.7 million in 2002 in research and development expenses.

### **Customer Service and Support**

Stereotaxis has contracted with Siemens to provide worldwide maintenance and support services to our customers for our integrated products. This allows us to leverage Siemens' extensive maintenance and support infrastructure for direct, on-site technical support activities, including its call center, customer support engineers and service parts logistics and delivery. It also provides a single point of contact for the customer and allows us to focus on providing installation, training, and back-up technical support. We have followed the same strategy with Philips and intend to do the same with other potential collaboration partners in the future.

Our back-up technical support includes a combination of on-line, telephone and on-site technical assistance services 24 hours a day, seven days a week. We have also hired service and support engineers with networking and medical equipment expertise, and have outsourced a portion of our support services. We offer several different levels of support to our customers, including basic hardware and software maintenance, extended product maintenance, and rapid response capability for both parts and service.

### **Manufacturing**

#### **NIOBE Systems**

Our manufacturing strategy for our NIOBE system is to sub-contract the manufacture of major components and to complete the final assembly and testing of those components in-house in order to control quality. This permits us to focus on our core competencies in magnet design, magnetic physics, magnetic instrument control and navigational algorithms. Approximately 8,000 square feet of our St. Louis, Missouri facility is dedicated to systems assembly, testing and inspection.

#### **Disposable Interventional Devices**

Our manufacturing strategy for disposable interventional devices is to outsource their manufacture through subcontracting and through our alliance with J&J and to expand partnerships for other interventional devices. We currently maintain pilot level manufacturing capability along with strong relationships with component level suppliers. We also manufacture prototype disposables to facilitate product development. We have approximately 5,000 square feet allocated to disposables manufacturing, assembly, testing and inspection with approximately 1,300 square feet of clean rooms in Maple Grove, Minnesota. We have also entered into a manufacturing agreement with Lake Region Manufacturing to provide high volume capability for guidewires.

## **Software**

The software components of the Stereotaxis System, including control and application software, are developed both internally and with integrated modules we purchase or license. We perform final testing of software products in-house prior to their commercial release.

## **General**

Our manufacturing facilities operate under processes that meet the FDA's requirements under the Quality System Regulation, or QSR. In 2003, the FDA audited our Maple Grove, Minnesota facility for regulatory compliance, and no deficiencies were noted. A European regulatory agency audited each facility in 2001, found them to be in compliance with the requirements of ISO 9001, and issued a formal certification from the ISO Registrar in January of 2002. If we fail to remain in compliance with the FDA or ISO 9001 standards, we may be required to cease all or part of our operations for some period of time until we can demonstrate that appropriate steps have been taken to comply with such standards. We cannot be certain that our facilities will comply with the FDA or ISO 9001 standards in future audits by regulatory authorities.

Our products require a number of complex operations, including multiple fabrication and assembly processes. We purchase both custom and off-the-shelf components from a number of certified suppliers and subject them to stringent quality processes. We apply periodic quality reviews of our suppliers and have established a supplier selection approval process. Some of the components necessary for the assembly of our products are supplied by a single supplier. Establishing additional or replacement suppliers for certain of those components cannot be done quickly. The disruption of the supply of components could cause a significant increase in the costs of these components, which could affect our profitability. We purchase components through both short and long-term supply arrangements and generally do not maintain large volumes of inventory. We currently have a long-term supply agreement for the supply of the permanent magnet assemblies used in our Stereotaxis System. We believe we have the ability to double our manufacturing capacity within six months to accommodate a significant increase in sales volume of our Stereotaxis System.

Lead times for materials and components ordered by us and our contract manufacturers vary and depend on factors such as the specific supplier, contract terms and demand for a component at a given time. We and our contract manufacturers acquire materials, complete standard subassemblies and assemble fully configured systems based on sales forecasts. If orders do not match forecasts, we and our contract manufacturers may have excess or inadequate inventory of materials and components. See "Factors That May Affect Future Results" for a discussion of various risks associated with our manufacturing strategy.

## **Sales and Marketing**

We market our products in the U.S. and Europe through a direct sales force of senior sales specialists, supported by account managers that provide training, clinical support, and other services to our customers. In addition, our strategic alliances form an important part of our sales and marketing strategy. We leverage the sales forces of Siemens and Philips to co-market integrated systems on a worldwide basis. This approach allows us to coordinate our marketing efforts with our strategic partners while still dealing directly with the customer. J&J will exclusively distribute our electrophysiology mapping and ablation catheters, co-developed pursuant to our alliance with them. We intend to increase our sales personnel and the number of account managers significantly over the next 24 months and to enter into distribution and sales representative arrangements to market our products in the rest of the world.

Our sales and marketing process has two important steps: (1) selling systems directly and through co-marketing agreements with our imaging partners, Siemens and Philips and through distributors; and (2) leveraging our installed base of systems to drive recurring sales of disposable interventional devices, software and service.

Step One: System sales. Our system sales strategy involves both direct selling, through our own sales force, and co-marketing with our strategic imaging partners, by leveraging these relationships to identify new or replacement cath labs being installed and then co-marketing integrated systems to the customer. Siemens and Philips have a major share of the cath lab installation market and therefore compete for a substantial number of potential cath lab installations on a worldwide basis, which gives us access to a large number of potential customers. These customers fall into three broad categories:

- leading research institutions with physician thought leaders who are interested in performing complex new procedures enabled by our system;
- high-volume commercial institutions interested in the efficiency benefits of our system; and
- medium volume regional centers that are competing intensely for patients, attempting to minimize referrals of complex cases to other centers and focusing on gaining market share in their regional markets.

Once we have identified potential customers, we approach capital equipment sales in five stages that bring significant predictability to our sales process. This allows us to measure the progress of each account in discrete steps through our sales funnel, and tailor our sales activity at each stage. The five-stage process includes the following, and has taken an average of 18 months for our 30 systems delivered to date:

- Build initial customer interest: presentation of our value proposition;
- Gain commitment: formal proposal with cost justification rationale;
- Secure capital budget allocation: customer begins formal budget approval process for system acquisition;
- Receive institutional approval: customer completes budget approval process and executes purchase order; and
- System installation: installation begins as part of overall cath lab construction or refurbishment.

As of December 31, 2004, we had received purchase orders and other commitments for approximately \$20 million of our Stereotaxis Systems. There can be no assurance that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside of our control. In addition, these orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays. All of our systems placed to date have been integrated with Siemens' digital x-ray fluoroscopy systems. We have several purchase orders with a commitment for installation with Philips and we anticipate installing systems integrated with Philips' digital x-ray fluoroscopy system beginning in early 2005.

Step Two: Recurring sales of disposable interventional devices, software and service. Each of our systems utilizes proprietary disposable interventional devices, both our own and those we are co-developing with strategic partners, as well as software tailored to specific clinical applications. We provide training and clinical support to users of our systems in order to increase their familiarity with system features and benefits, and thereby increase usage. More frequent usage should result in increased consumption of disposable interventional devices and software. While a basic one-year warranty is included with each system, we believe service contracts providing for enhanced levels of support and service beyond the basic warranty will become an important additional source of revenue.

Our relationships with physician thought leaders in the fields of interventional cardiology and electrophysiology are an important component of our selling efforts. These relationships are typically built around research

collaborations, and they enable us to better understand and articulate the most useful features and benefits of our system, and to develop new solutions to long-standing challenges in interventional medicine. We will continue to seek support and collaboration from highly regarded physicians in order to perform important research and accelerate market awareness and adoption of our systems.

## **Reimbursement**

We believe that substantially all of the procedures, whether commercial or in clinical trials, conducted in the U.S. with the Stereotaxis System have been reimbursed to date and that substantially all commercial procedures in Europe have been reimbursed. We expect that third-party payors will reimburse, under existing billing codes, our line of guidewires, as well as our line of ablation catheters and those on which we are collaborating with J&J. We expect healthcare facilities in the U.S. to bill various third-party payors, such as Medicare, Medicaid, other government programs and private insurers, for services performed with our products. We believe that procedures performed using our products, or targeted for use by products that do not yet have regulatory clearance or approval, are generally already reimbursable under government programs and most private plans. Accordingly, we believe providers in the U.S. will generally not be required to obtain new billing authorizations or codes in order to be compensated for performing medically necessary procedures using our products on insured patients. We cannot assure you that reimbursement policies of third-party payors will not change in the future with respect to some or all of the procedures using the Stereotaxis System. See "Factors That May Affect Future Results" for a discussion of various risks associated with reimbursement from third-party payors.

## **Intellectual Property**

Our strategy is to patent the technology, inventions and improvements that we consider important to the development of our business. As a result, we believe that we have an extensive patent portfolio that protects the fundamental scope of our technology, including our magnet technology, navigational methods, procedures, systems, disposables interventional devices and our 3D integration technology. As of December 31, 2004, we had 42 issued U.S. patents, eight exclusively licensed U.S. patents, one exclusively licensed non-U.S. patent and three non-exclusively licensed U.S. patents. In addition, we had 69 pending U.S. patent applications, 17 pending non-U.S. patent applications, and six Patent Cooperation Treaty applications. We also have a number of invention disclosures under consideration and several applications that are being prepared for filing. Accordingly, we anticipate that the number of pending U.S. patent applications will increase.

Our patent portfolio covering magnet systems, including our NIOBE cardiology magnet system, is comprised of eight issued patents and 11 pending applications. We have 16 issued patents and 19 pending applications covering methods of magnetically controlling magnetic medical devices, including the fundamental method of magnetically orienting and mechanically advancing devices in the body. In addition, we have 10 issued patents and 18 pending applications covering disposable interventional devices, including electrophysiology catheters, guidewires, atherectomy devices, neuro and other devices and our CARDIODRIVE automated catheter advancer. Finally, we have 19 pending patent applications for our disposable interventional devices, interfaces and navigation techniques that cover non-magnetic medical navigation.

The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. One or more of the above patent applications may be denied. In addition, our issued patents may be challenged, based on prior art circumvented or otherwise not provide protection for the products we develop. Furthermore, we may not be able to obtain patent licenses from third parties required for the development of new products for use with our system. We also note that U.S. patents and patent applications may be subject to interference proceedings and U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent

application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the entire loss of our patent or the relevant portion of our patent and not just with respect to that particular infringer. Any litigation to enforce or defend our patents rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations.

It would be technically difficult and costly to reverse engineer our Stereotaxis System, which contains numerous complex algorithms that control our disposable devices inside the magnetic fields generated by the Stereotaxis System. We further believe that our patent portfolio is broad enough in scope to enable us to obtain legal relief if any entity not licensed by us attempted to market disposable devices that can be navigated by the NIOBE system. We have developed plastic software keys, or smart chips, that allow our system to recognize specific disposable interventional devices in order to prevent unauthorized use of our system. We anticipate that these smart chips will be an important part of our disposable interventional device strategy going forward.

We have also developed substantial know-how in magnet design, magnetic physics and magnetic instrument control that was developed in connection with the development of the Stereotaxis System, which we maintain as trade secrets. This centers around our proprietary magnet design, which is a critical aspect of our ability to design, manufacture and install a cost-effective cardiology magnet system that is small enough to be installed in a standard cath lab.

We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside partners and other advisers to execute nondisclosure and assignment of invention agreements upon commencement of their employment or engagement, through which we seek to protect our intellectual property. These agreements to protect our unpatented technology provide only limited and possibly inadequate protection of our rights. Third parties may therefore be able to use our unpatented technology, reducing our ability to compete. In addition, employees, consultants and other parties to these agreements may breach them and adequate remedies may not be available to us for their breaches. Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert the attention of management and key personnel from our business operations. We also generally seek confidentiality agreements from third parties that receive our confidential data or materials.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technologies and products as well as successfully defending these patents against third-party challenges. Some of our technology was co-developed with third parties and these third parties may claim rights in our intellectual property. We may also be liable for patent infringement by third parties whose products we use or combine with ours and for which we have no right to indemnification. In addition, many countries, including certain European countries, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties in some circumstances (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. We expect to face expensive and time-consuming infringement actions, validity challenges and other intellectual property claims and proceedings, which are frequent in the medical device industry, and which divert management's

attention from our business. There are other risks associated with our patent portfolio and other intellectual property. Please refer to "Factors That May Affect Future Results" for a more complete description of these risks.

University of Virginia. We have exclusively licensed six patents related to the field of magnetically guiding an element through the body and viewing it for medical use from the University of Virginia Patent Foundation. The UVA patents address earlier versions of our system which we do not believe are essential to the protection of our current business activities, although one of these patents could be construed to cover some of our current activities. To date, we have expensed a five percent royalty on sales of products that might arguably be covered by this patent and our business model assumes continued payment of this royalty to UVA. However, we have become aware of prior art that caused us to question the validity of this patent, and as a result, we have initiated re-examination of the patent in the U.S. Patent and Trademark Office. If this reexamination finds the patent partially or completely invalid, our royalty obligations under the license agreement could be reduced or eliminated. We believe that our other patents would be sufficient to protect our technology in that event.

## **Competition**

The markets for medical devices are intensely competitive and are characterized by rapid technological advances, frequent new product introductions, evolving industry standards and price erosion.

We consider our primary competition to be existing manual catheter-based interventional techniques and surgical procedures. To our knowledge, we are the only company that has commercialized remote, digital and direct control of the working tip of catheters and guidewires for interventional use. Our success depends in part on convincing hospitals and physicians to convert existing interventional procedures to computer-assisted procedures.

We expect to face competition from companies that are developing new approaches and products for use in interventional procedures, including robotic approaches that may be directly competitive with our technology. Many of these companies have an established presence in the field of interventional cardiology, including the major imaging, capital equipment and disposables companies that are currently selling products in the cath lab. We also face competition from companies who currently market or are developing drugs or gene therapies to treat the conditions for which our products are intended.

We believe that the primary competitive factors in the market we address are capability, safety, efficacy, ease of use, price, quality, reliability and effective sales, support, training and service. The length of time required for products to be developed and to receive regulatory and reimbursement approval is also an important competitive factor. We believe Stereotaxis has an important "first mover" advantage in establishing clinical standards in these areas. See "Factors That May Affect Future Results" for a discussion of other competitive risks facing our business.

## **Government Regulation**

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, these laws and their interpretations are subject to change.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the billing practices of healthcare providers and the marketing of healthcare products. The federal government also has increased funding in recent years to fight healthcare fraud, and various agencies, such as the U.S. Department of

Justice, the Office of Inspector General of the Department of Health and Human Services, or OIG, and state Medicaid fraud control units, are coordinating their enforcement efforts.

We believe that we have structured our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business and most frequently cited in enforcement actions.

### **U.S. Food and Drug Administration, or FDA, Regulation**

The Food and Drug Administration strictly regulates the medical devices we produce under the authority of the Federal Food, Drug and Cosmetic Act, or FFDCA, the regulations promulgated under the FFDCA, and other federal and state statutes and regulations. The FFDCA governs, among other things, the pre-clinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, post market reporting and advertising and promotion of medical devices.

Our medical devices are categorized under the statutory framework described in the FFDCA. This framework is a risk-based system which classifies medical devices into three classes from lowest risk (Class I) to highest risk (Class III). In general, Class I and II devices are either exempt from the need for FDA clearance or cleared for marketing through a premarket notification, or 510(k), process. Our devices that are considered to be general tools, such as our NIOBE cardiology magnet system and our suite of guidewires, or that provide diagnostic information, such as our TANGENT electrophysiology mapping catheters, are subject to 510(k) requirements. These devices are cleared for use as general tools which have utility in a variety of interventional procedures. Our therapeutic devices, such as our HELIOS ablation catheters, are subject to the premarket application, or PMA, process.

If clinical data is needed to support a marketing application for our devices, generally, an investigational device exemption, or IDE, is assembled and submitted to the FDA. The FDA reviews and must approve the IDE before the study can begin. In addition, the study must be approved by an Institutional Review Board covering each clinical site. When all approvals are obtained, we initiate a clinical study to evaluate the device. Following completion of the study, we collect, analyze, and present the data in an appropriate submission to the FDA, either a 510(k) or PMA.

Under the 510(k) process, the FDA determines whether or not the device is "substantially equivalent" to a predicate device. In making this determination, the FDA compares both the new device and the predicate device. If the two devices are comparable in intended use, safety, and effectiveness, the device may be cleared for marketing.

Under the PMA process, the FDA examines detailed data relating to the safety and effectiveness of the device. This information includes design, development, manufacture, labeling, advertising, pre-clinical testing, and clinical study data. Prior to approving the PMA, the FDA generally will conduct an inspection of the facilities producing the device and one or more clinical sites where the study was conducted. The facility inspection evaluates the company's readiness to commercially produce and distribute the device. The inspection includes an evaluation of compliance under the Quality System Regulation (QSR). Under certain circumstances, the FDA may convene an advisory panel meeting to seek review of the data presented in the PMA. If the FDA's evaluation is favorable, the PMA is approved, and we can market the device in the U.S. The FDA may approve the PMA with conditions, such as post-market surveillance requirements.

We evaluate changes made following 510(k) clearance or PMA approval for significance and if appropriate, make a subsequent submission to the FDA. In the case of a significant change being made to a 510(k) device, we submit a new 510(k). For a PMA device, we will either need approval through a PMA supplement or will need to notify the FDA.



For our 510(k) devices, we design the submission to cover multiple models or variations in order to minimize the number of submissions. For our PMA devices, we rely upon the PMA approvals of our strategic partners to utilize the PMA supplement regulatory path rather than pursue an original PMA. Because of the differences in the amount of data and numbers of patients in clinical trials, a PMA supplement process is often much shorter than the amount of time and data required for approval of an original PMA.

Currently our NIOBE cardiology magnet system, NAVIGANT advanced user interface, CARDIODRIVE automated catheter advancer, family of CRONUS coronary guidewires, and TANGENT electrophysiology mapping catheter have been cleared by the FDA to be used in interventional procedures. In addition, we have received the CE Mark for our HELIOS electrophysiology ablation catheter and, in the U.S., we have completed clinical trials in 2004 and expect to subsequently file a PMA.

We are subject to risks associated with U.S. government regulation. See "Factors That May Affect Future Results" for a discussion of the specific regulatory risks associated with our business.

### **Foreign Regulation**

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval in any foreign country in which we plan to market our products may harm our ability to generate revenue and harm our business.

The primary regulatory environment in Europe is that of the European Union, which consists of 25 countries encompassing most of the major countries in Europe. The European Union requires that manufacturers of medical products obtain the right to affix the CE Mark to their products before selling them in member countries of the European Union. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE Mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE Mark on its products and commercially distribute those products throughout the European Union.

We have received the right to affix the CE Mark to each of our products that has received 510(k) clearance in the U.S. and also for our HELIOS ablation catheter. We are pursuing the right to affix the CE mark to certain guidewires that have received 510(k) clearance in the U.S. If we modify existing products or develop new products in the future, including new devices, we will need to apply for permission to affix the CE Mark to such products. We will be subject to regulatory audits, currently conducted biannually, in order to maintain any CE Mark permissions we have already obtained. We cannot be certain that we will be able to obtain permission to affix the CE Mark for new or modified products or that we will continue to meet the quality and safety standards required to maintain the permissions we have already received. If we are unable to maintain permission to affix the CE Mark to our products, we will no longer be able to sell our products in member countries of the European Union.

In addition, through Siemens, we intend to submit an application for regulatory approval to commence a clinical study in 2005 with the Japanese Ministry of Health, Labor and Welfare for commercial use of the Stereotaxis System in Japan. Siemens has agreed to coordinate the regulatory approval process and act as distributor for our NIOBE cardiology magnet system and NAVIGANT advanced user interface in Japan, and we have begun to formulate our clinical plans for regulatory approval. We are currently formulating our clinical and regulatory plans for China and anticipate using Siemens to coordinate regulatory approval and distribute our products in China. We will evaluate regulatory approval in other foreign countries on an opportunistic basis.

## **Anti-Kickback Statute**

The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the OIG to issue a series of regulations, known as the "safe harbors" which it did, beginning in July of 1991. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against sales personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. As part of our compliance program, we review our sales contracts and marketing materials to help assure compliance with the Anti-Kickback Statute and similar state laws. However, we cannot rule out the possibility that the government or other third parties could interpret these laws differently and assert otherwise.

## **HIPAA**

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

In addition to creating the two new federal healthcare crimes, HIPAA also establishes uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. Two standards have been promulgated under HIPAA: the Standards for Privacy of

Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, and the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures. In addition, the Security Standards will require covered entities to implement certain security measures to safeguard certain electronic health information by April 21, 2005. Although we believe we are not a covered entity and therefore do not need to comply with these standards, our customers generally are covered entities and frequently ask us to comply with certain aspects of these standards. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards may entail significant and costly changes for us. If we fail to comply with these standards, it is possible that we could be subject to criminal penalties.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our operations and procedures to comply with the more stringent state laws, which may entail significant and costly changes for us. We believe that we are in compliance with such state laws and regulations. However, if we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

### **Federal False Claims Act**

Another trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act's "whistleblower" or "qui tam" provisions. Those provisions allow a private individual to bring actions on behalf of the government alleging that the defendant has defrauded the federal government. The government must decide whether to intervene in the lawsuit and to become the primary prosecutor. If it declines to do so, the individual may choose to pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. If the individual's litigation is successful, the individual is entitled to no less than 15%, but no more than 30%, of whatever amount the government recovers. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted laws modeled after the federal False Claims Act.

When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the federal False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. Although simple negligence should not give rise to liability, submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could result in substantial civil liability. The False Claims Act has been used to assert liability on the basis of inadequate care, improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. We are unable to predict whether we could be subject to actions under the False Claims Act, or the impact of such actions. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly affect our financial performance.

### **Certificate of Need Laws**

In approximately two-thirds of the states, a certificate of need or similar regulatory approval is required prior to the acquisition of high-cost capital items or various types of advanced medical equipment, such as our Stereotaxis System. At present, many of the states in which we sell Stereotaxis Systems have laws that require institutions located in those states to obtain a certificate of need in connection with the purchase of our system, and some of our purchase orders are conditioned upon our customer's receipt of necessary certificate of need approval. Certificate of need laws were enacted to contain rising health care costs, prevent the unnecessary duplication of health resources, and increase

patient access for health services. In practice, certificate of need laws have prevented hospitals and other providers who have been unable to obtain a certificate of need from acquiring new equipment or offering new services. A further increase in the number of states regulating our business through certificate of need or similar programs could adversely affect us. Moreover, some states may have additional requirements. For example, we understand that California's certificate of need law also incorporates seismic safety requirements which must be met before a hospital can acquire our Stereotaxis System.

### **Employees**

As of December 31, 2004, we had 140 employees, 49 of whom were engaged directly in research and development, 30 in manufacturing and service, 12 in regulatory, clinical affairs and quality activities, 35 in sales and marketing activities and 14 in general administrative and accounting activities. None of our employees is covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

### **ITEM 2. PROPERTIES**

We lease approximately 31,000 square feet of manufacturing and office space in St. Louis, Missouri. The St. Louis facility is leased through December 31, 2005. On November 18, 2004, we entered into an office lease agreement under which we will lease space in a new building to be constructed in St. Louis. Once the building is completed, we will move our current St. Louis, Missouri operations to the leased space in the new building. The lease for the new premises is effective December 1, 2005 and has a term of ten years, with two renewal options of three years each. The minimum annual rental under the terms of the lease ranges from approximately \$705,000 in 2006 to approximately \$1,177,000 in 2015, including rent for expansion space provided for in the lease.

We also lease approximately 10,000 square feet in Maple Grove, Minnesota. The Minnesota facility is leased through December 31, 2006. We believe that the Minnesota facility will be adequate to meet our needs through 2006.

### **ITEM 3. LEGAL PROCEEDINGS**

We are involved from time to time in various lawsuits and claims arising in the normal course of business. Although the outcomes of these lawsuits and claims are uncertain, we do not believe any of them will have a material adverse effect on our business, financial condition or results of operations.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the quarter ended December 31, 2004.

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### PRICE RANGE OF COMMON STOCK

Our common stock has been traded on The Nasdaq Stock Market under the symbol "STXS" since August 12, 2004. The following table sets forth the high and low closing prices of our common stock for the periods indicated and reported by Nasdaq.

| <u>Quarter</u>                        | <u>High</u> | <u>Low</u> |
|---------------------------------------|-------------|------------|
| <b>Year Ended December 31, 2004:</b>  |             |            |
| August 12, 2004 to September 30, 2004 | \$12.44     | \$7.50     |
| Fourth Quarter                        | 10.89       | 8.43       |

As of February 28, 2005, there were approximately 176 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

### DIVIDEND POLICY

We have never declared or paid any cash dividends. We currently expect to retain earnings for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends for the next several years.

The information required by this item regarding equity compensation is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

### USE OF PROCEEDS FROM IPO

We effected the initial public offering of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-115253) that was declared effective by the Securities and Exchange Commission on August 11, 2004 and pursuant to which shares were offered on August 12, 2004.

The net proceeds from the offering, after an underwriting discount and other expenses, were approximately \$41.4 million. We have begun to use, and intend to continue to use, the net proceeds of the offering for general corporate purposes, including: working capital; continued sales, marketing and clinical support initiatives relating to the commercialization of our products; and continued research and development.

Pending other uses, we have invested the remaining net proceeds of the offering primarily in short-term, investment grade, interest-bearing instruments.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data has been derived from, and should be read in conjunction with our consolidated financial statements and the accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report. The selected data in this section is not intended to replace the consolidated financial statements. Historical results are not indicative of the results to be expected in the future.

|   | Year Ended December 31, |                 |                 |                 |                |
|---|-------------------------|-----------------|-----------------|-----------------|----------------|
|   | 2004                    | 2003            | 2002            | 2001            | 2000           |
| <b>Consolidated Statements of Operations Data:</b>            |                         |                 |                 |                 |                |
| Sales   | \$ 18,816,860           | \$ 5,014,877    | \$ 18,900       | \$ -            | \$ -           |
| Cost of Sales   | 10,672,262              | 4,051,313       | 39,760          | -               | -              |
| Gross Profit  | 8,144,598               | 963,564         | (20,860)        | -               | -              |
| Operating costs and expenses:                                 |                         |                 |                 |                 |                |
| Research and development                                      | 18,437,108              | 13,886,462      | 14,742,015      | 14,359,131      | 8,871,585      |
| General and administrative                                    | 6,315,987               | 5,028,142       | 4,528,637       | 2,645,563       | 1,625,621      |
| Sales and marketing   | 10,964,925              | 5,999,310       | 2,230,565       | 951,280         | 386,229        |
| Total operating costs and expenses                            | 35,718,020              | 24,913,914      | 21,501,217      | 17,955,974      | 10,883,435     |
| Loss from operations  | (27,573,422)            | (23,950,350)    | (21,522,077)    | (17,955,974)    | (10,883,435)   |
| Interest and other income, net                                | 315,953                 | (86,487)        | 63,419          | 950,776         | 1,334,319      |
| Net loss  | \$ (27,257,469)         | \$ (24,036,837) | \$ (21,458,658) | \$ (17,005,198) | \$ (9,549,116) |
| Basic and diluted net loss per share (1)                      | \$ (2.38)               | \$ (18.37)      | \$ (19.21)      | \$ (23.01)      | \$ (20.64)     |
| Shares used in computing basic and diluted net loss per share | 11,470,310              | 1,308,805       | 1,117,301       | 739,088         | 462,616        |
| <b>Consolidated Balance Sheet Data:</b>                       |                         |                 |                 |                 |                |
| Cash, cash equivalents and short-term investments             | \$ 45,648,834           | \$ 26,480,612   | \$ 28,834,123   | \$ 30,452,205   | \$ 24,712,254  |
| Working Capital   | 49,672,005              | 22,764,719      | 25,483,149      | 26,660,162      | 22,859,357     |
| Total Assets  | 71,187,756              | 37,323,419      | 32,920,872      | 31,750,413      | 25,170,000     |
| Long-term debt, less current maturities                       | 1,000,000               | 2,243,768       | 2,281,321       | -               | -              |
| Accumulated deficit   | (114,673,234)           | (87,415,765)    | (63,378,928)    | (41,920,270)    | (24,915,072)   |
| Total stockholders' equity                                    | 58,394,468              | 25,266,428      | 24,006,646      | 27,476,496      | 23,255,756     |

(1) The one-for-3.6 reverse stock split effective as of July 2004 has been reflected in the calculation of the basic and diluted net loss per share for all periods presented above.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-K. Operating results are not necessarily indicative of results that may occur in future periods.*

*This report includes various forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption "Factors That May Affect Future Results." Forward-looking statements discuss matters that are not historical facts. Forward-looking statements*

*include, but are not limited to, discussions regarding our operating strategy, sales and marketing strategy, regulatory strategy, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would," or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.*

## **Overview**

Stereotaxis designs, manufactures and markets an advanced cardiology instrument control system for use in a hospital's interventional surgical suite to enhance the treatment of coronary artery disease and arrhythmias. The Stereotaxis System is designed to enable physicians to complete more complex interventional procedures by providing image guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using computer-controlled, externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, shorter procedure time and reduced x-ray exposure. The core components of the Stereotaxis system have received regulatory clearance in the U.S. and Europe.

We believe that our system represents a revolutionary technology in the interventional surgical suite, or "cath lab", and has the potential to become the standard of care for a broad range of complex cardiology procedures. We also believe that our system is the only technology to be commercialized that allows remote, computerized control of catheters and guidewires directly at their working tip. We also believe that our technology represents an important advance in the ongoing trend toward digital instrumentation in the cath lab and provides substantial, clinically important improvements and cost efficiencies over manual interventional methods, which require years of physician training and often result in long and unpredictable procedure times and sub-optimal therapeutic outcomes.

From our inception in June 1990 through 2002, our principal activities were obtaining capital, business development, performing research and development activities, funding prototype development, funding clinical trials and funding collaborations to integrate our products with other interventional technologies. Accordingly, we were classified as a development stage company for accounting purposes through December 31, 2002.

Our initial focus was on the development of neurosurgical applications for our technology, including delivery of devices to specific sites within the brain. During that time, we primarily devoted our resources primary to developing prototypes and performing research and development activities in this area. Following receipt of FDA approval to begin human clinical trials in the field of brain biopsies, we successfully completed our initial human clinical procedures in this area in late 1998. Over the next two years, we shifted our primary focus to developing applications for our technology to treat cardiovascular diseases because of the significantly larger market opportunities for such applications. During 2003, following receipt of marketing clearance from the FDA for our current system, we emerged from the development stage and began to generate revenue from the placement of investigational systems and the commercial launch of our cardiology system in the U.S. and Europe.

In August 2004, we completed an initial public offering in which we issued and sold 5,500,000 shares of common stock. In September 2004, the underwriters exercised an option to purchase 462,352 additional shares. In connection with the initial public offering (including the over-allotment option exercise), we received approximately \$41.4 million in net proceeds. Prior to our initial public offering, we funded our operations primarily through private equity financings, supplemented by bank financing. Since our inception, we have generated significant losses. As of December 31, 2004, we had incurred cumulative net losses of approximately \$114.7 million. We expect to incur

additional losses through the first half of 2006 as we continue the development and commercialization of our products, conduct our research and development activities and advance new products into clinical development from our existing research programs. We expect to use substantial financial resources from our initial public offering to expand our sales and marketing and customer support activities.

We have alliances with each of Siemens AG Medical Solutions, Philips Medical Systems and Biosense Webster, Inc., a subsidiary of J&J, through which we are integrating our Stereotaxis System with market leading digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices, in order to continue to develop new solutions in the cath lab. Each of these alliances provides for coordination of our sales and marketing activities with those of our partners. In addition, Siemens and Philips have agreed to provide worldwide service for our integrated systems. Siemens and J&J also invested in our convertible preferred stock, which was converted into common stock as a result of the initial public offering.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We review our estimates and judgments on an on-going basis. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the following accounting policies are critical to the judgments and estimates we use in preparing our financial statements.

#### ***Revenue Recognition***

We recognize systems revenue from system sales made directly to end users upon installation, provided there are no uncertainties regarding acceptance, persuasive evidence of an arrangement exists, the sales price is fixed or determinable, and collection of the related receivable is reasonably ensured. When installation is required for revenue recognition, the determination of acceptance is made by the Company's employees based on criteria set forth in the terms of the sale. Revenue from system sales made to distributors is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. If uncertainties exist regarding collectability, the Company recognizes revenue when those uncertainties are resolved. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Co-placement fees from strategic partners for the Company's collaboration in certain sales and marketing efforts will be recognized as revenue when earned under the terms of the respective agreements. Revenue from services, whether sold individually or as a separable unit of accounting in a multi-element arrangement, is deferred and amortized over the service period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. The Company recognizes revenue from disposable device sales or accessories upon shipment, and an appropriate reserve for returns is established. Other revenue represents a system sale for which the cost of production was charged to research and development costs in 2002 and 2001.

For arrangements with multiple deliverables, we allocate the total revenue to each deliverable based on its relative fair value in accordance with the provisions of Emerging Issues Task Force (EITF) Issue No. 00-21, "*Revenue Arrangements with Multiple Deliverables*" and recognize revenue for each separate element as the above criteria are met.



### ***Stock-based Compensation***

We account for employee and director stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*. Stock options issued to non-employees, principally individuals who provide scientific advisory services, are recorded at their fair value as determined in accordance with SFAS No. 123 and EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and amortized over the service period.

Stock compensation expense, which is a noncash charge, results from stock option grants made to employees at exercise prices below the deemed fair value of the underlying common stock, and from stock option grants made to non-employees at the fair value of the option granted. The fair value of options granted was determined using the Black-Scholes valuation method which gives consideration to the estimated value of the underlying stock at the date of grant, the exercise price of the option, the expected dividend yield and volatility of the underlying stock, the expected life of the option and the corresponding risk-free interest rate. When we were a private company, the deemed fair value of the underlying common stock was determined by management and the Board of Directors based on their best estimates using information from preferred stock financing transactions or other significant changes in the business. Stock compensation expense is amortized over the vesting period of the underlying option, generally two to four years. Unearned deferred compensation for non-employees is periodically remeasured through the vesting date.

The amount of deferred compensation expense to be recorded in future periods may decrease if unvested options for which we have recorded deferred compensation are subsequently cancelled or expire, or may increase if the fair market value of our stock increases or we make additional grants of non-qualified stock options to members of our scientific advisory board or other non-employees.

### ***Deferred Income Taxes***

We account for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. We have established a valuation allowance against the entire amount of our deferred tax assets because we are not able to conclude, due to our history of operating losses, that it is more likely than not that we will be able to realize any portion of the deferred tax assets.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable losses, limitations imposed by Section 382 of the Internal Revenue Code and projections for future losses over periods which the deferred tax assets are deductible, management determined that a 100% valuation allowance of deferred tax assets was appropriate.

### ***Valuation of Inventory***

We value our inventory at the lower of the actual cost of our inventory, as determined using the first-in, first-out (FIFO) method, or its current estimated market value. We periodically review our physical inventory for obsolete items and provide a reserve upon identification of potential obsolete items.

## ***Intangible Assets***

Intangible assets are comprised of purchased technology with a finite life. The acquisition cost of purchased technology is capitalized and amortized over its useful life in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*. We review the assigned useful life on an on-going basis for consistency with the period over which cash flows are expected to be generated from the asset and consider the potential for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The process of estimating useful lives and evaluating potential impairment is subjective and requires management to exercise judgment in making assumptions related to future cash flows and discount rates.

## **Results of Operations**

### ***Comparison of the Years ended December 31, 2004 and 2003***

*Revenues.* Revenues increased to \$18.8 million for the year ended December 31, 2004 from \$5.0 million for the year ended December 31, 2003, an increase of approximately 275%. Revenues from sales of systems increased to \$17.2 million for the year ended December 31, 2004 from \$3.8 million for the year ended December 31, 2003, an increase of approximately 352%. Revenues from the sale of systems increased primarily because we sold 22 systems in 2004 compared to eight systems in 2003 and because of an increase in average selling price. Revenues from sales of disposable interventional devices, service and accessories increased to \$1.6 million for the year ended December 31, 2004 from \$481,000 for the year ended December 31, 2003, an increase of approximately 232%. This increase was attributable to the increased base of installed systems.

*Cost of Revenues.* Cost of revenues increased to \$10.7 million for the year ended December 31, 2004 from \$4.1 million for the year ended December 31, 2003, an increase of approximately 163%. This increase in cost of revenues was attributable primarily to the increased number of systems sold and associated cost of goods sold for those systems, offset by an approximate 17% reduction in average cost per system recognized. As a percentage of our revenues, cost of revenues, excluding "Other revenue," was 57% in the year ended December 31, 2004 compared to 95% in the year ended December 31, 2003. The improvement in the cost of revenue as a percentage of revenues was primarily a result of previously mentioned cost reduction as well as an increase in average selling price per system.

*Research and Development Expenses.* Research and development expenses increased to \$18.4 million for the year ended December 31, 2004 from \$13.9 million for the year ended December 31, 2003, an increase of approximately 33%. The increase was due principally to an increase in the number of research and development projects with our strategic partners, primarily related to disposable interventional devices, further development of the Niobe platform technology, and salary and benefits for additional personnel performing research activities. In addition, during the year ended December 31, 2004 we recognized an offset to our development expenses under our agreement with Philips relating to the integration of our system with Philips' digital x-ray fluoroscopy system. Any payments received from Philips in excess of amounts recognized as earned are included in accrued liabilities on the balance sheet.

*General and Administrative Expenses.* General and administrative expenses increased to \$6.3 million for the year ended December 31, 2004 from \$5.0 million for the year ended December 31, 2003, an increase of 26%. The increase was due to an increase in our business activity related to the commercialization of our products, including personnel and clinical trials as well as legal and other costs.

*Sales and Marketing Expenses.* Sales and marketing expenses increased to \$11.0 million for the year ended December 31, 2004 from \$6.0 million for the year ended December 31, 2003, an increase of approximately 83%. The increase related primarily to increased salary, benefits and travel expenses associated with hiring additional sales personnel and expanded marketing programs.

*Interest Income.* Interest income increased approximately 116% to \$811,000 for the year ended December 31, 2004 from \$375,000 for the year ended December 31, 2003. Interest income increased due to greater invested balances and higher realized rates on short-term investments during the year ended December 31, 2004.

*Interest Expense.* Interest expense remained relatively unchanged as the average borrowings and average rates were relatively unchanged.

### ***Comparison of the Years ended December 31, 2003 and 2002***

*Revenues.* We generated \$5.0 million in revenue in 2003 compared to \$18,900 in 2002. This increase in revenues was attributable to the commencement of commercial sales of our systems following regulatory approval in 2003. As described above, we recognized revenue in 2003 from the sale of eight systems, including one predecessor system for which the cost of production was charged to research and development for previous years. This system, which is reflected as "other revenue" in our financial statements, is similar to a prototype in that it was placed prior to our receipt of FDA approval and was developed and installed primarily to demonstrate the effectiveness of our new technology. Because of uncertainties regarding whether payment would be ultimately received for this system, the full cost was expensed to research and development during the system's construction, principally during 2001. In 2003, following acceptance and the commencement of commercial use, the customer paid for the predecessor system. As a result, we recognized revenue in 2003 upon payment for the system.

*Cost of Revenues.* Cost of revenues increased to \$4.1 million in 2003 from \$39,800 in 2002. This increase in cost of revenues was attributable primarily to the commencement of sales of our NIOBE system and associated cost of goods sold for those systems. As a percentage of our revenues, cost of revenues, excluding "Other revenue," was 95% in the year ended December 31, 2003. In 2002, our cost of revenues greatly exceeded our revenues because we did not have commercial revenues from the sale of systems in 2002.

*Research and Development Expenses.* Research and development expenses decreased to \$13.9 million in 2003 from \$14.7 million in 2002, a decrease of approximately 6%. Our research and development expenses were higher in 2002 primarily because we were developing prototypes required for regulatory approval of our products.

*General and Administrative Expenses.* General and administrative expenses increased to \$5.0 million in 2003 from \$4.5 million in 2002, an increase of approximately 11%. The increase from 2002 to 2003 was directly attributable to personnel additions made to support the commercial launch of our products in 2003.

*Sales and Marketing Expenses.* Sales and marketing expenses increased to \$6.0 million in 2003 from \$2.2 million in 2002, an increase of approximately 169%. The increase related primarily to increased salary, benefits and travel expenses associated with the hiring of additional sales personnel and the expansion of our marketing programs.

*Interest Income.* Interest income decreased to \$375,000 for 2003 from \$434,000 for 2002, a decrease of approximately 14%. The decrease was primarily the result of lower interest rates realized on balances invested.

*Interest Expense.* Interest expense increased to \$462,000 for 2003 from \$371,000 for 2002, an increase of approximately 25%. The increase was primarily the result of higher interest expense from increased borrowings under various Silicon Valley Bank lines of credit.

### **Income Taxes**

Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. Accordingly, net deferred tax assets have been fully offset by valuation allowances as of December 31, 2004, 2003 and 2002 to reflect these uncertainties. As of December 31, 2004, we had federal and state net operating

loss carryforwards of approximately \$108.1 million and federal research and development credit carryforwards of approximately \$2.1 million. The net operating loss and research and development credit carryforwards will expire on various dates beginning in 2005 through 2024, respectively, if not utilized. We may not be able to utilize certain of these loss carryforwards and credits prior to their expiration. Of the \$108.1 million net operating loss, \$5.6 million is limited as to its use prior to December 31, 2007.

## Liquidity and Capital Resources

Prior to our initial public offering, we financed our operations almost entirely from the private sale of equity securities, totaling approximately \$127 million net of offering expenses. To a much lesser extent, we also financed our operations through working capital and equipment financing loans. We raised funds from these sources because, as a developing company, we were not able to fund our activities solely from the cash provided by our operations.

In August 2004, we completed an initial public offering in which we issued and sold 5,500,000 shares of common stock. In September 2004, the underwriters exercised their option to purchase an additional 462,352 shares. In connection with the initial public offering and over-allotment exercise, we received approximately \$41.4 million in net proceeds. At December 31, 2004, we had working capital of approximately \$49.7 million, compared to \$22.8 million at December 31, 2003.

Liquidity refers to the liquid financial assets available to fund our business operations and pay for near-term obligations. These liquid financial assets consist of cash and cash equivalents, as well as investments. In addition to our cash and cash equivalent balances, we maintained \$28.7 million and \$5.1 million of investments in corporate debt securities, U.S. government agency notes and commercial paper at December 31, 2004 and 2003, respectively.

The following table summarizes our cash flow by operating, investing and financing activities for each of years ended December 31, 2004, 2003 and 2002 (in thousands):

|  | <u>2004</u> | <u>2003</u> | <u>2002</u> |
|--|-------------|-------------|-------------|
| Cash Flow provided by (used in) Operating Activities | \$(31,814)  | \$(24,469)  | \$(22,029)  |
| Cash Flow provided by (used in) Investing Activities | (29,654)    | (7,182)     | 1,480       |
| Cash Flow provided by (used in) Financing Activities | 57,019      | 24,174      | 20,719      |

*Net cash (used in) operating activities.* We used approximately \$31.8 million, \$24.5 million and \$22.0 million of cash in operating activities during the year ended December 31, 2004, 2003 and 2002, respectively, primarily as a result of operating losses during these periods. Cash used for working capital purposes increased to \$5.9 million during the year ended December 31, 2004 from \$1.4 million during the year ended December 31, 2003 primarily as a result of an increase in accounts receivable from increased sales and billings for sales deposits from customers offset by an increase in deferred revenue related to installed systems on which revenue has not yet been recognized and from deposits received from customers.

*Net cash provided by (used in) investing activities.* We used approximately \$29.7 million of cash for investing activities during the year ended December 31, 2004, substantially all for the purchase of investments, compared to \$7.2 million during the year ended December 31, 2003. The 2003 investing activities included purchases of property, plant and equipment of approximately \$2.1 million. Cash from investing activities of \$1.5 million during the year ended December 31, 2002 was substantially all from the sale of short-term investments.

*Net cash provided by financing activities.* We received approximately \$57.0 million from financing activities during the year ended December 31, 2004, primarily as a result of the completion of our initial public offering (and exercise by the underwriters of their over-allotment option) in August and September 2004 and the sale of our Series E-2 preferred stock and related common stock warrants in January and February 2004. We also realized \$2.0 million in proceeds from the issuance of long-term debt from our equipment loan with Silicon Valley Bank and repaid approximately \$2.6 million of equipment loans and revolving credit facility. We received approximately \$24.2 million from financing activities during 2003, primarily as a result of the sale of our Series D-2 preferred stock and related common stock warrants and from the sale of our Series E and E-1 preferred stock in January, June and December 2003. We received approximately \$20.7 million from financing activities during 2002, primarily as a result of the sale of our Series D-1 and D-2 preferred stock and related common stock warrants in January and December 2002.

As of December 31, 2004, we had outstanding balances under various equipment loan agreements with Silicon Valley Bank, consisting of an aggregate of \$1.9 million. In April 2004, we entered into an amendment to our working capital revolving line of credit to increase our borrowing capacity from \$3.0 to \$8.0 million. As of December 31, 2004 we had no outstanding borrowings under this working capital line of credit and had borrowing capacity of \$8.0 million, subject to collateralization by qualifying receivables and inventory balances with a maturity of April 2006.

These credit facilities with Silicon Valley Bank are secured by substantially all of our assets. The credit agreements include customary affirmative, negative and financial covenants. For example, we are restricted from incurring additional debt, disposing of or pledging our assets, entering into merger or acquisition agreements, making certain investments, allowing fundamental changes to our business, ownership, management or business locations, and from making certain payments in respect of stock or other ownership interests, such as dividends and stock repurchases. Under our loan arrangements, we are required to maintain a ratio of "quick" assets (cash, cash equivalents, accounts receivable and short-term investments) to current liabilities minus deferred revenue of at least 1.5 to 1. We were also required to maintain a minimum tangible net worth of at least \$50.0 million as of the end of each calendar month. Effective November 3, 2004, this minimum tangible net worth requirement was amended to \$30 million. We are also required under the credit agreements to maintain our primary operating account and the majority of our cash and investment balances in accounts with the lender. We are in compliance with all covenants of this agreement.

In August 2003, we issued a \$2.0 million cumulative convertible pay-in-kind 8%, 3-year note to Siemens pursuant to an agreement under which we purchased certain technology. The outstanding principal, together with accrued and unpaid interest, of \$2.17 million automatically converted into 271,739 shares of common stock upon the closing of our initial public offering, at a conversion price equal to \$8.00 per share, the initial price to the public of our shares of common stock in the offering.

We expect to have negative cash flow from operations through at least the first half of 2006. Throughout 2005, we expect to continue the development and commercialization of our products, the continuation of our research and development programs and the advancement of new products into clinical development. We have substantially increased the overall level of our research and development expenses from their levels in 2003 as a result of the alliance agreements described above and otherwise, and we expect that these expenses will continue at substantially their current levels in the near term. In addition, our selling, general and administrative expenses will continue to increase in order to support our product commercialization efforts and to implement procedures required by our status as a public company. Until we can generate significant cash flow from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of our initial public offering, private sales of our equity securities and working capital and equipment financing loans. In the future, we may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financings. We cannot accurately predict the timing and amount of our utilization of capital, which will depend on a number of factors outside of our control.

While we believe our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital equipment requirements through at least the next 12 months, we cannot assure you that we will not require additional financing before that time. We also cannot assure you that such additional financing will be available on a timely basis on terms acceptable to us or at all, or that such financing will not be dilutive to our stockholders. If adequate funds are not available to us, we could be required to delay development or commercialization of new products, to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or to reduce the marketing, customer support or other resources devoted to our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

### Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

### Contractual Obligations

The following table summarizes all significant contractual payment obligations by payment due date:

| Contractual Obligations          | Payments by Period<br>(In thousands) |                |                |                 | Total    |
|----------------------------------|--------------------------------------|----------------|----------------|-----------------|----------|
|                                  | Under<br>1 Year                      | 1 - 3<br>Years | 3 - 5<br>Years | Over<br>5 Years |          |
| Long-term debt (1)               | \$ 910                               | \$1,000        | \$ -           | \$ -            | \$ 1,910 |
| Operating leases                 | 792                                  | 1,493          | 1,638          | 6,550           | 10,473   |
| Capital leases                   | 11                                   | 9              | 7              | -               | 27       |
| Research and alliance agreements | 6,160                                | 1,679          | 350            | -               | 8,189    |
| Total                            | \$7,873                              | \$4,181        | \$1,995        | \$6,550         | \$20,599 |

(1) We have not included interest payable on our revolving credit agreement in these amounts because it is calculated at a variable rate.

### Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), "Share-Based Payment". SFAS No. 123(R) supersedes APB Opinion No. 25, which requires recognition of an expense when goods or services are provided. SFAS No. 123(R) requires the determination of the fair value of the share-based compensation at the grant date and the recognition of the related expense over the period in which the share-based compensation vests. We are required to adopt the provisions of SFAS No. 123(R) effective July 1, 2005. These new accounting rules will lead to a decrease in reported earnings and we have not yet determined the exact impact SFAS No. 123(R) will have on our financial statements.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs," an amendment of ARB No. 43. The amendments clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges and require the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal years beginning after the date SFAS No. 151 was issued. The adoption of SFAS No. 151 is not expected to have a material impact on the Company's financial statements.

## **Factors That May Affect Future Results**

### **Hospital decision-makers may not purchase our Stereotaxis System or may think that it is too expensive.**

The market for our products and related technology is not well established. To achieve continued sales, hospitals must purchase our products, and in particular, our NIOBE cardiology magnet system. The NIOBE cardiology magnet system, which is the core of our Stereotaxis System, is a novel device, and hospitals and physicians are traditionally slow to adopt new products and treatment practices. Moreover, the Stereotaxis System is an expensive piece of capital equipment, representing a significant portion of the cost of a new or replacement cath lab. If hospitals do not widely adopt our Stereotaxis System, or if they decide that it is too expensive, we may never become profitable. Any failure to sell as many Stereotaxis Systems as our business plan requires could also have a seriously detrimental impact on our results of operations, financial condition and cash flow.

### **Physicians may not use our products if they do not believe they are safe and effective.**

We believe that physicians will not use our products unless they determine that the Stereotaxis System provides a safe, effective and preferable alternative to interventional methods in general use today. Currently, there is only limited clinical data on the Stereotaxis System with which to assess safety and efficacy. If longer-term patient studies or clinical experience indicate that treatment with our system or products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be subject to significant liability. Further, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from the use of these new products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If physicians do not use our products, we likely will not become profitable or generate sufficient cash to survive as a going concern.

### **Our collaborations with Siemens, Philips and J&J may fail, or we may not be able to enter into additional partnerships or collaborations in the future.**

We are collaborating with Siemens, Philips and J&J to integrate our instrument control technology with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our Stereotaxis System. For the immediate future, a significant portion of our revenues from system sales will be derived from these integrated products. In addition, each of Siemens and Philips has agreed to provide post-installation maintenance and support services to our customers for our integrated systems.

Our product commercialization plans could be disrupted, leading to lower than expected revenue and a material and adverse impact on our results of operations and cash flow, if:

- any of our collaboration partners delays or fails in the integration of its technology with our Stereotaxis System as planned;

- any of our collaboration partners does not co-market and co-promote our integrated products diligently or does not provide maintenance and support services as we expect; or
- we become involved in disputes with one or more of our collaboration partners regarding our collaborations.

Siemens, Philips and J&J, as well as some of our other collaborators, are large, global organizations with diverse product lines and interests that may diverge from our interests in commercializing our products. Accordingly, our collaborators may not devote adequate resources to our products, or may experience financial difficulties, change their business strategy or undergo a business combination that may affect their willingness or ability to fulfill their obligations to us. In particular, we have had only limited experience with respect to the integration of our system with Philips' imaging products.

The failure of one or more of our collaborations could have a material adverse effect on our financial condition, results of operations and cash flow. In addition, if we are unable to enter into additional partnerships in the future, or if these partnerships fail, our ability to develop and commercialize products could be impacted negatively and our revenues could be adversely affected.

**You may have difficulty evaluating our business and operating results because we are still in the early stages of commercializing our products.**

We have been engaged in research and product development since our inception in 1990. Our initial focus was on the development of neurosurgical applications for our technology, and during the first several years following our inception, we devoted our resources primarily to developing prototypes and performing research and development activities in this area. Starting around 1998, we shifted our primary focus over the next two years to developing applications for our technology to treat cardiovascular disease and, in 2003, began limited commercial shipments of products we developed for treatment in this area. To date, our investments in our products have produced relatively little revenue, and our operating expenses are high relative to that revenue. Our lack of a significant operating history also impairs an investor's ability to make a comparative evaluation of us, our products and our prospects.

**We have limited experience selling, marketing and distributing products, which could impair our ability to increase revenues.**

We currently market our products in the U.S. and Europe through a direct sales force of sales specialists, supported by account managers that provide training, clinical support, and other services to our customers. If we are unable to increase our sales force significantly in the foreseeable future, we may be unable to generate the revenues we have projected in our business plan. Factors that may inhibit our sales and marketing efforts include:

- our inability to recruit and retain adequate numbers of qualified sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals and physicians to purchase and use our products;
- unforeseen costs associated with maintaining and expanding an independent sales and marketing organization; and
- increased government scrutiny with respect to marketing activities in the health care industry.

In addition, if we fail to effectively use distributors or contract sales persons for distribution of our products where appropriate, our revenues and profitability would be adversely affected.



**We may lose or fail to attract physician “thought leaders”.**

Our research and development efforts and our marketing strategy depend heavily on obtaining support and collaboration from highly regarded physicians at leading commercial and research hospitals. If we are unable to gain such support and collaboration, our ability to market the Stereotaxis System and, as a result, our financial condition, results of operations and cash flow could be materially and adversely affected.

**We may not be able to rapidly train physicians in numbers sufficient to generate adequate demand for our products.**

In order for physicians to learn to use the Stereotaxis System, they must attend one or more training sessions. Market acceptance could be delayed by lack of physician willingness to attend training sessions or by the time required to complete this training. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse impact on our financial condition and cash flow.

**Customers may choose to purchase competing products and not ours.**

Our products must compete with established manual interventional methods. These methods are widely accepted in the medical community, have a long history of use and do not require the purchase of an additional expensive piece of capital equipment. In addition, many of the medical conditions that can be treated using our products can also be treated with existing pharmaceuticals or other medical devices and procedures. Many of these alternative treatments are widely accepted in the medical community and have a long history of use.

We also face competition from companies that are developing drugs or other medical devices or procedures to treat the conditions for which our products are intended. The medical device and pharmaceutical industries make significant investments in research and development, and innovation is rapid and continuous. For example, we are aware that two private companies are developing non-magnetic assisted navigation devices that could compete directly with the Stereotaxis System. However, to the best of our knowledge, these products have not been commercialized. If these or other new products or technologies emerge that provide the same or superior benefits as our products at equal or lesser cost, it could render our products obsolete or unmarketable. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

Most of our other competitors also have longer operating histories, significantly greater financial, technical, marketing and other resources, greater name recognition and a larger base of customers than we do. In addition, as the markets for medical devices develop, additional competitors could enter the market. We cannot assure you that we will be able to compete successfully against existing or new competitors. Our revenues would be reduced or eliminated if our competitors develop and market products that are more effective and less expensive than our products.

**If we are unable to fulfill our current purchase orders and other commitments on a timely basis or at all, we may not be able to achieve future sales growth.**

We currently have outstanding purchase orders and other commitments for our systems. There can be no assurance that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays. The installation process for a Stereotaxis System is long and involves multiple stages, the completion of many of which are outside of our control. If we experience any failures or delays in completing the installation of these systems, our reputation would suffer and we may not be able to sell additional systems.

Substantial delays in the installation process also increase the risk that a customer would attempt to cancel a purchase order. This would have a negative effect on our revenues and results of operations.

**We will likely experience long and variable sales cycles, which could result in substantial fluctuations in our quarterly results of operations.**

We anticipate that our system will continue to have a lengthy sales cycle because it consists of a relatively expensive piece of capital equipment, the purchase of which requires the approval of senior management at hospitals, inclusion in the hospitals' cath lab budget process for capital expenditures, and, in some instances, a certificate of need from the state or other regulatory approval. In addition, assembly and installation of the system has typically taken six to eight months after a customer agreed to purchase a system. Assembly and installation could take even longer if our system is part of a larger construction project at the customer site. These factors may contribute to substantial fluctuations in our quarterly operating results, particularly in the near term and during any other periods in which our sales volume is relatively low. As a result, in future quarters our operating results could fall below the expectations of securities analysts or investors, in which event our stock price would likely decrease.

**If the magnetic fields generated by our system are not compatible with, or interfere with, other widely used equipment in the cath lab, sales of our products would be negatively affected.**

Our system generates magnetic fields that directly govern the motion of the internal, or working, tip of disposable interventional devices. If other equipment in the cath lab or elsewhere in a hospital is incompatible with the magnetic fields generated by our system, or if our system interferes with such equipment, we may be required to install additional shielding, which may be expensive and which may not solve the problem. For example, in two hospitals where we installed our system, it interfered with equipment located in adjacent rooms. In order to correct these particular situations, we installed additional shielding and made other adjustments to our equipment. Although we have modified our shielding approach, if magnetic interference is a problem at additional institutions, it would increase our installation costs at those institutions and could limit the number of hospitals that would be willing to purchase and install our systems, either of which would adversely affect our financial condition, results of operations and cash flow.

**The use of our products could result in product liability claims that could be expensive, divert management's attention and harm our reputation and business.**

Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we could face product liability claims if the use of our products were to cause injury or death. The coverage limits of our product liability insurance policies may not be adequate to cover future claims, and we may be unable to maintain product liability insurance in the future at satisfactory rates or adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could divert management's attention, result in significant legal defense costs, significant harm to our reputation and a decline in revenues.

**Our costs could substantially increase if we receive a significant number of warranty claims.**

We generally warrant each of our products against defects in materials and workmanship for a period of 12 months from the acceptance of our product by a customer. We have only a limited history of commercial placements from which to judge our rate of warranty claims. If product returns or warranty claims increase, we could incur unanticipated additional expenditures for parts and service. In addition, our reputation and goodwill in the cath lab market could be damaged. While we have established reserves for liability associated with product warranties, unforeseen warranty exposure in excess of those reserves could materially and adversely affect our financial condition, results of operations and cash flow.

**We may not generate cash from operations necessary to commercialize our existing products and invest in new products.**

If we require additional funds to meet our working capital and capital expenditure needs in the future, we cannot be certain that we will be able to obtain additional financing on favorable terms or at all. If we need additional capital and cannot raise it on acceptable terms, we may not be able to, among other things:

- enhance our existing products or develop new ones;
- expand our operations;
- hire, train and retain employees; or
- respond to competitive pressures or unanticipated capital requirements.

Our failure to do any of these things could result in lower revenues and adversely affect our financial condition and results of operations, and we may have to curtail or cease operations.

**We have incurred substantial losses in the past and may not be profitable in the future.**

We have incurred substantial net losses since inception, and we expect to incur substantial additional and increasing net losses for at least the next several years as we seek additional regulatory approvals, launch new products and generally scale up our sales, marketing and manufacturing operations to commercialize our products. We had net losses of approximately \$27.3 million in 2004, \$24.0 million in 2003, \$21.5 million in 2002, and at December 31, 2004 we had an accumulated deficit of approximately \$114.7 million. A small portion of our accumulated deficit is attributable to investments in development of products for neurosurgical applications, which was our primary focus in the first several years after our inception in 1990. Because we may not be successful in completing the development or commercialization of our technology in these areas, your return on these investments may be limited. Moreover, the extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If we require more time than we expect to generate significant revenues and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability could negatively impact the market price of our common stock. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Furthermore, even if we achieve significant revenues, we may choose to pursue a strategy of increasing market penetration and presence at the expense of profitability.

**Our reliance on contract manufacturers and on suppliers, and in some cases, a single supplier, could harm our ability to meet demand for our products in a timely manner or within budget.**

We depend on contract manufacturers to produce most of the components of our systems and other products. We also depend on various third party suppliers for the magnets we use in our NIOBE cardiology magnet systems and for our guidewires and electrophysiology catheters. In addition, some of the components necessary for the assembly of our products are currently provided to us by a single supplier, including the magnets for our NIOBE cardiology magnet system, and we generally do not maintain large volumes of inventory. Our reliance on these third parties involves a number of risks, including, among other things, the risk that:

- we may not be able to control the quality and cost of our system or respond to unanticipated changes and increases in customer orders;
- we may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems; and
- we may not be able to find new or alternative components for our use or reconfigure our system and manufacturing processes in a timely manner if the components necessary for our system become unavailable.

If any of these risks materialize, it could significantly increase our costs and impair product delivery.

In addition, if these manufacturers or suppliers stop providing us with the components or services necessary for the operation of our business, we may not be able to identify alternate sources in a timely fashion. Any transition to alternate manufacturers or suppliers would likely result in operational problems and increased expenses and could delay the shipment of, or limit our ability to provide, our products. We cannot assure you that we would be able to enter into agreements with new manufacturers or suppliers on commercially reasonable terms or at all. Additionally, obtaining components from a new supplier may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. Any disruptions in product flow may harm our ability to generate revenues, lead to customer dissatisfaction, damage our reputation and result in additional costs or cancellation of orders by our customers.

We also rely on our collaboration partner, J&J, to manufacture a number of disposable interventional devices for use with our Stereotaxis System. If J&J cannot manufacture sufficient quantities of disposable interventional devices to meet customer demand, or if their manufacturing processes are disrupted, our revenues and profitability would be adversely affected.

**Risks associated with international manufacturing and trade could negatively impact the availability and cost of our products because our magnets, one of our key system components, are sourced from Japan.**

We purchase the permanent magnets for our NIOBE cardiology magnet system from a manufacturer that uses material produced in Japan, and certain of the production work for these magnets is performed for this manufacturer in China. In addition, we purchase our magnets for our disposable interventional devices directly from a manufacturer in Japan, and a number of other components for our system in foreign jurisdictions, including components sourced locally in connection with installations. Any event causing a disruption of imports, including the imposition of import restrictions, could adversely affect our business. The flow of components from our vendors could also be adversely affected by financial or political instability in any of the countries in which the goods we purchase are manufactured, if the instability affects the production or export of product components from those countries. Trade restrictions in the form of tariffs or quotas, or both, could also affect the importation of those product components and could increase the cost and reduce the supply of products available to us. In addition, decreases in the value of the U.S. dollar against foreign currencies could increase the cost of products we purchase from overseas vendors.

**We have limited experience in manufacturing and assembling our products and may encounter problems at our manufacturing facilities or otherwise experience manufacturing delays that could result in lost revenue.**

We do not have extensive experience in manufacturing, assembling or testing our products on a commercial scale. In addition, for our NIOBE cardiology magnet systems, we subcontract the manufacturing of major components and complete the final assembly and testing of those components in-house. As a result, we may be unable to meet the expected future demand for our Stereotaxis System. We may also experience quality problems, substantial costs and unexpected delays in our efforts to upgrade and expand our manufacturing, assembly and testing capabilities. If we incur delays due to quality problems or other unexpected events, we will be unable to produce a sufficient supply of systems necessary to meet our future growth expectations. In addition, we are manufacturing a limited number of our disposable interventional devices ourselves in a pilot manufacturing program and intend to continue to subcontract the manufacture of others to third parties. In order to do so, we will need to retain qualified employees for our assembly and testing operations. In addition, we are dependent on the facilities we lease in St. Louis, Missouri and Maple Grove, Minnesota in order to manufacture and assemble certain products. We could encounter problems at either of these facilities, which could delay or prevent us from assembling or testing our products or maintaining our pilot manufacturing capabilities or otherwise conducting operations. We are also moving our St. Louis operations to new facilities in the St. Louis area in 2005. Moving to a new facility could disrupt our

systems assembly or testing activities and divert the attention of our management and other key personnel from our business operations.

**We may be unable to protect our technology from use by third parties.**

Our commercial success will depend in part on obtaining patent and other intellectual property right protection for the technologies contained in our products and on successfully defending these rights against third party challenges. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We cannot assure you that we will obtain the patent protection we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office, and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office, which proceedings could result in either loss of the patent or denial of the patent application or loss, or reduction in the scope of one or more of the claims of, the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

Some of our technology was developed in conjunction with third parties, and thus there is a risk that a third party may claim rights in our intellectual property. Outside the U.S., we rely on third-party payment services for the payment of foreign patent annuities and other fees. Non-payment or delay in payment of such fees, whether intentional or unintentional, may result in loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. We also cannot assure you that we will be able to develop additional patentable technologies. If we fail to obtain adequate patent protection for our technology, or if any protection we obtain becomes limited or invalidated, others may be able to make and sell competing products, impairing our competitive position.

Our trade secrets, nondisclosure agreements and other contractual provisions to protect unpatented technology provide only limited and possibly inadequate protection of our rights. As a result, third parties may be able to use our unpatented technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products or in commercial relationships with us may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach.

Our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the U.S., particularly in the field of medical products and procedures.

**Third parties may assert that we are infringing their intellectual property rights.**

Successfully commercializing our products will depend in part on not infringing patents held by third parties. It is possible that one or more of our products, including those that we have developed in conjunction with third parties, infringes existing patents. We may also be liable for patent infringement by third parties whose products we

use or combine with our own and for which we have no right to indemnification. In addition, because patent applications are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. Whether a product infringes a patent involves complex legal and factual issues and may not become clear until finally determined by a court in litigation. Our competitors may assert that our products infringe patents held by them. Moreover, as the number of competitors in our market grows, the possibility of a patent infringement claim against us increases. If we were not successful in obtaining a license or redesigning our products, we could be subject to litigation. If we lose in this kind of litigation, a court could require us to pay substantial damages or prohibit us from using technologies essential to our products covered by third-party patents. An inability to use technologies essential to our products would have a material adverse effect on our financial condition, results of operations and cash flow and could undermine our ability to continue operating as a going concern.

**Expensive intellectual property litigation is frequent in the medical device industry.**

Infringement actions, validity challenges and other intellectual property claims and proceedings, whether with or without merit, can be expensive and time-consuming and would divert management's attention from our business. We have incurred, and expect to continue to incur, substantial costs in obtaining patents and may have to incur substantial costs defending our proprietary rights. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

**We may not be able to obtain all the licenses from third parties necessary for the development of new products.**

As we develop additional disposable interventional devices for use with our system, we may find it advisable or necessary to seek licenses from third parties who hold patents covering technology used in specific interventional procedures. If we cannot obtain those licenses, we could be forced to try to design around those patents at additional cost or abandon the product altogether, which could adversely affect revenues and results of operations. If we have to abandon a product, our ability to develop and grow our business in new directions and markets would be adversely affected.

**Our products and related technologies can be applied in different industries, and we may fail to focus on the most profitable areas.**

The Stereotaxis System is designed to have the potential for expanded applications beyond interventional cardiology and electrophysiology, including interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine. However, we have limited financial and managerial resources and therefore may be required to focus on products in selected industries and to forego efforts with regard to other products and industries. Our decisions may not produce viable commercial products and may divert our resources from more profitable market opportunities. Moreover, we may devote resources to developing products in these additional areas but may be unable to justify the value proposition or otherwise develop a commercial market for products we develop in these areas, if any. In that case, the return on investment in these additional areas may be limited, which could negatively affect our results of operations.

**We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their

work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

**If we or our strategic partners fail to obtain or maintain necessary FDA clearances for our medical device products, or if such clearances are delayed, we will be unable to continue to commercially distribute and market our products.**

Our products are medical devices that are subject to extensive regulation in the U.S. and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either 510(k) clearance or pre-market approval, or PMA, from the U.S. Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act. The FDA's 510(k) clearance process usually takes from four to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain, generally taking from one to three years or even longer. Although we have 510(k) clearance for our current Stereotaxis System, including a limited number of disposable interventional devices, and are able to market our system commercially in the U.S., our business model relies significantly on revenues from additional disposable interventional devices for which there is no current FDA clearance or approval. We cannot market our unapproved disposable interventional devices in the U.S. until the necessary clearance or approvals from the FDA have been received and can only place these devices with research institutions for permitted investigational use. In addition, we are working with third parties with whom we are co-developing disposable products. In some cases, these companies are responsible for obtaining appropriate regulatory clearance for these disposable devices. If these clearances or approvals are not received or are substantially delayed, we may not be able to successfully market our system to as many institutions as we currently expect, which could have a material adverse impact on our financial condition, results of operations and cash flow.

Furthermore, obtaining 510(k) clearances, pre-market approvals, or PMAs, or premarket approval supplements, or PMA supplements, from the FDA could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect non-clinical data, conduct clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a 510(k) clearance or PMA or PMA supplement approval, the clearance or approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. Obtaining regulatory approvals in foreign markets entails similar risks and uncertainties and can involve additional product testing and additional administrative review periods. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected. Also, a failure to obtain approvals may limit our ability to grow domestically and internationally.

**If we or our strategic partners fail to obtain regulatory approvals in other countries for products under development, we will not be able to commercialize these products in those countries.**

In order to market our products outside of the U.S., we and our strategic partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA approval in the U.S. In addition, we are relying

on our strategic partners in some instances to assist us in this regulatory approval process in countries outside the U.S. and Europe, for example, in Japan.

**We may fail to comply with continuing regulatory requirements of the FDA and other authorities and become subject to substantial penalties.**

Even after product approval, we must comply with continuing regulation by the FDA and other authorities, including the FDA's Quality System Regulation, or QSR, requirements, labeling and promotional requirements and medical device adverse event and other reporting requirements. For example, as a result of our own ongoing quality testing, in January 2004 we voluntarily recalled our CRONUS guidewires. Any failure to comply with continuing regulation by the FDA or other authorities could result in enforcement action that may include suspension or withdrawal of regulatory approvals, recalling products, ceasing product marketing, seizure and detention of products, paying significant fines and penalties, criminal prosecution and similar actions that could limit product sales, delay product shipment and harm our profitability.

Additionally, any modification to an FDA 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance. Device modifications to a PMA approved device or its labeling may require either a new PMA or PMA supplement approval, which could be a costly and lengthy process. In the future, we may modify our products after they have received clearance or approval, and we may determine that new clearance or approval is unnecessary. We cannot assure you that the FDA would agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek clearance or approval for any modification, we also may be required to cease marketing or recall the modified product until we obtain FDA clearance or approval which could also limit product sales, delay product shipment and harm our profitability. In addition, Congress could amend the Federal Food, Drug and Cosmetic Act, and the FDA could modify its regulations promulgated under this law in a way so as to make ongoing regulatory compliance more burdensome and difficult.

In many foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of these regulations are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our products to be qualified before procedures performed using our products become eligible for reimbursement. Failure to receive, or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations. Due to the movement toward harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide single regulatory system. We cannot predict the timing of this harmonization and its effect on us. Adapting our business to changing regulatory systems could have a material adverse effect on our business, financial condition and results of operations. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

**Our suppliers or we may fail to comply with the FDA quality system regulation.**

Our manufacturing processes must comply with the FDA's quality system regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the QSR through inspections. We cannot assure you that we would pass such an inspection. Failure to pass such an inspection could force a shut down of our manufacturing operations, a recall of our products or the imposition of other sanctions, which would significantly harm our revenues and profitability. Further, we cannot assure you that our key component suppliers are or will continue to be in compliance



with applicable regulatory requirements and will not encounter any manufacturing difficulties. Any failure to comply with the FDA's QSR by us or our suppliers could significantly harm our available inventory and product sales.

**Software defects may be discovered in our products.**

Our products incorporate sophisticated computer software. Complex software frequently contains errors, especially when first introduced. Because our products are designed to be used to perform complex interventional procedures, we expect that physicians and hospitals will have an increased sensitivity to the potential for software defects. We cannot assure you that our software will not experience errors or performance problems in the future. If we experience software errors or performance problems, we would likely also experience:

- loss of revenue;
- delay in market acceptance of our products;
- damage to our reputation;
- additional regulatory filings;
- product recalls;
- increased service or warranty costs; and/or
- product liability claims relating to the software defects.

**If we fail to comply with health care regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.**

While we do not control referrals of health care services or bill directly to Medicare, Medicaid or other third-party payors, due to the breadth of many health care laws and regulations, we cannot assure you that they will not apply to our business. We could be subject to health care fraud and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- federal self-referral laws, such as STARK, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, to achieve compliance with applicable federal and state privacy, security, and electronic transaction laws, we may be required to modify our operations with respect to the handling of patient information. Implementing these modifications may prove costly. At this time, we are not able to determine the full consequences to us, including the total cost of compliance, of these various federal and state laws.

**The application of state certificate of need regulations and compliance with federal and state licensing requirements could substantially limit our ability to sell our products and grow our business.**

Some states require health care providers to obtain a certificate of need or similar regulatory approval prior to the acquisition of high-cost capital items such as our Stereotaxis System. In many cases, a limited number of these certificates are available. As a result of this limited availability, hospitals and other health care providers may be unable to obtain a certificate of need for the purchase of our Stereotaxis System. Further, our sales cycle for the Stereotaxis System is typically longer in certificate of need states due to the time it takes our customers to obtain the required approvals. In addition, our customers must meet various federal and state regulatory and/or accreditation requirements in order to receive payments from government-sponsored health care programs such as Medicare and Medicaid, receive full reimbursement from third party payors and maintain their customers. Any lapse by our customers in maintaining appropriate licensure, certification or accreditation, or the failure of our customers to satisfy the other necessary requirements under government-sponsored health care programs, could cause our sales to decline.

**Hospitals or physicians may be unable to obtain reimbursement from third-party payors for procedures using the Stereotaxis System, or reimbursement for procedures may be insufficient to recoup the costs of purchasing our products.**

We expect that U.S. hospitals will continue to bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for procedures performed with our products, including the costs of the disposable interventional devices used in these procedures. If in the future our disposable interventional devices do not fall within U.S. reimbursement categories and our procedures are not reimbursed, or if the reimbursement is insufficient to cover the costs of purchasing our system and related disposable interventional devices, the adoption of our systems and products would be significantly slowed or halted, and we may be unable to generate sufficient sales to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored health care payment systems and third-party payors. In both the U.S. and foreign markets health care cost-containment efforts are prevalent and are expected to continue. These efforts could reduce levels of reimbursement available for procedures involving our products and, therefore, reduce overall demand for our products as well. A failure to generate sufficient sales could have a material adverse impact on our financial condition, results of operations and cash flow.

**We may lose our key personnel or fail to attract and retain additional personnel.**

We are highly dependent on the principal members of our management and scientific staff, in particular Bevil J. Hogg, our President and Chief Executive Officer, Michael P. Kaminski, our Chief Operating Officer and William M. Kelley, one of our directors. Mr. Kelley has extensive experience in the medical device industry, and we believe his

industry contacts enable us to have proposals reviewed by key hospital decision-makers earlier in the sales process than may otherwise be the case. In order to pursue our plans and accommodate planned growth, we may choose to hire additional personnel. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for qualified personnel among technology and healthcare companies and universities. The loss of any of these persons or our inability to attract and retain other qualified personnel could harm our business and our ability to compete. In addition, Douglas M. Bruce, our Senior Vice President, Research & Development, coordinates our scientific staff and the research and development projects they undertake; the loss of Mr. Bruce or other members of our scientific staff may significantly delay or prevent product development and other business objectives.

**Our growth will place a significant strain on our resources, and if we fail to manage our growth, our ability to develop, market and sell our products will be harmed.**

Our business plan contemplates a period of substantial growth and business activity. This growth and activity will likely result in new and increased responsibilities for management personnel and place significant strain upon our operating and financial systems and resources. To accommodate our growth and compete effectively, we will be required to improve our information systems, create additional procedures and controls and expand, train, motivate and manage our work force. We cannot be certain that our personnel, systems, procedures and controls will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products.

**We face currency and other risks associated with international sales.**

We intend to continue to devote significant efforts to marketing our systems and products outside of the U.S. This strategy will expose us to numerous risks associated with international operations, which could adversely affect our results of operations and financial condition, including the following:

- currency fluctuations that could impact the demand for our products or result in currency exchange losses;
- export restrictions, tariff and trade regulations and foreign tax laws;
- customs duties, export quotas or other trade restrictions;
- economic and political instability; and
- shipping delays.

In addition, contracts may be difficult to enforce and receivables difficult to collect through a foreign country's legal system.

#### **Risks Related To Our Common Stock**

**Our principal stockholders continue to own a large percentage of our voting stock, and they have the ability to substantially influence matters requiring stockholder approval.**

As of December 31, 2004, our executive officers, directors and individuals or entities affiliated with them beneficially own or control a substantial percentage of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

**We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.**

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to return our future earnings to fund the development and growth of our business. In addition, the terms of our loan agreement prohibit us from declaring dividends without the prior consent of our lender. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**Our certificate of incorporation and bylaws, Delaware law and one of our alliance agreements contain provisions that could discourage a takeover.**

Our certificate of incorporation and bylaws and Delaware law contain provisions that might enable our management to resist a takeover. These provisions may:

- discourage, delay or prevent a change in the control of our company or a change in our management;
- adversely affect the voting power of holders of common stock; and
- limit the price that investors might be willing to pay in the future for shares of our common stock.

In addition, under our alliance with J&J, either party may terminate the alliance under certain circumstances involving a "change of control" of Stereotaxis. Any termination must be effected within 90 days of the change of control, but would be effective one year after the change of control. If we terminate under this provision, we must pay a termination fee to J&J equal to 5% of the total equity value of Stereotaxis in the change of control transaction, up to a maximum of \$10 million. We also agreed to notify J&J if we reasonably consider that we are engaged in substantive discussions in respect of the sale of the company or substantially all of our assets. These provisions may similarly discourage a takeover and negatively affect our share price as described above.

**Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.**

Sales of substantial amounts of our common stock in the public market, or the perception that substantial sales may be made, could cause the market price of our common stock to decline. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

As of December 31, 2004, we had outstanding 27,187,042 shares of common stock.

**Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules are creating uncertainty for public companies. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Maintaining appropriate standards of corporate governance and public disclosure may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, if we fail to comply with new or changed laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business and reputation may be harmed.

**Our future operating results may be below securities analysts' or investors' expectations, which could cause our stock price to decline.**

The revenue and income potential of our products and our business model are unproven, and we may be unable to generate significant revenues or grow at the rate expected by securities analysts or investors. In addition, our costs may be higher than we, securities analysts or investors expect. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations will suffer, which in turn could cause our stock price to decline. Our results of operations will depend upon numerous factors, including:

- demand for our products;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- the success of our collaborations with Siemens, Philips and J&J and others;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- our ability to obtain regulatory clearances or approvals for our new products; and
- our ability to obtain and protect proprietary rights.

Our operating results in any particular period may not be a reliable indication of our future performance. In some future quarters, our operating results may be below the expectations of securities analysts or investors. If this occurs, the price of our common stock will likely decline.

**We expect that the price of our common stock could fluctuate substantially, possibly resulting in class action securities litigation.**

We have only been publicly traded since August 12, 2004. A limited number of our shares trade actively in the market. The market price of our common stock will be affected by a number of factors, including:

- actual or anticipated variations in our results of operations or those of our competitors;
- the receipt or denial of regulatory approvals;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- changes in earnings estimates or recommendations by securities analysts or our failure to achieve analyst earnings estimates; and
- developments in our industry.

The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Class action securities litigation, if instituted against us, could result in substantial costs and a diversion of our management resources, which could significantly harm our business.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We have exposure to currency fluctuations. We operate mainly in the U.S. and Europe and we expect to continue to sell our products outside of the U.S. We expect to transact this business primarily in U.S. dollars and in

Euros, although we may transact business in other currencies to a lesser extent. Future fluctuations in the value of these currencies may affect the price competitiveness of our products. In addition, because we have a relatively long installation cycle for our systems, we will be subject to risk of currency fluctuations between the time we execute a purchase order and the time we deliver the system and collect payments under the order, which could adversely affect our operating margins. We have not hedged exposures in foreign currencies or entered into any other derivative instruments. As a result, we will be exposed to some exchange risks for foreign currencies. For example, if the currency exchange rate were to fluctuate by 10%, our revenues could be affected by as much as 2 to 3%.

We also have exposure to interest rate risk related to our investment portfolio and our borrowings. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing the risk of loss.

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since the majority of our investments are in short-term debt instruments. We invest our excess cash primarily in U.S. government securities and marketable debt securities of financial institutions and corporations with strong credit ratings. These instruments generally have maturities of two years or less when acquired. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions. Accordingly, we believe that while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

We do not believe that inflation has had a material adverse impact on our business or operating results during the periods covered by this report.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Financial Statements**

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All other schedules have been omitted because they are not applicable or the required information is shown in the Financial Statements or the Notes thereto.

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
Stereotaxis, Inc.

We have audited the accompanying balance sheets of Stereotaxis, Inc. (the "Company") as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our audit also included the financial statement schedule listed in the Index at Item 15(a). Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Stereotaxis, Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

St. Louis, Missouri  
February 18, 2005



# STEREOTAXIS, INC.

## BALANCE SHEETS

|  | December 31,         |                      |
|--|----------------------|----------------------|
|  | 2004                 | 2003                 |
| <b>Assets</b>  |                      |                      |
| Current assets:  |                      |                      |
| Cash and cash equivalents  | \$ 16,907,516        | \$ 21,356,247        |
| Short-term investments   | 28,741,318           | 5,124,365            |
| Accounts receivable, net of allowance for uncollectible accounts of<br>\$146,223 and \$116,725 in 2004 and 2003, respectively  | 8,621,205            | 559,721              |
| Current portion of long-term receivables   | 168,795              | 155,331              |
| Inventories  | 4,673,994            | 4,430,228            |
| Prepaid expenses and other current assets  | 2,351,058            | 876,264              |
| Total current assets   | 61,463,886           | 32,502,156           |
| Property and equipment, net  | 1,557,847            | 2,309,467            |
| Intangible assets, net   | 1,811,111            | 1,944,444            |
| Long-term receivables  | 337,590              | 465,993              |
| Other assets   | 120,697              | 101,359              |
| Long-term investments  | 5,896,625            | -                    |
| Total assets   | <u>\$ 71,187,756</u> | <u>\$ 37,323,419</u> |
| <b>Liabilities and stockholders' equity</b>  |                      |                      |
| Current liabilities:   |                      |                      |
| Current maturities of long-term debt   | \$ 910,434           | \$ 2,289,314         |
| Accounts payable   | 2,129,473            | 1,697,497            |
| Accrued liabilities  | 5,710,216            | 4,936,233            |
| Deferred contract revenue  | 3,041,758            | 814,393              |
| Total current liabilities  | 11,791,881           | 9,737,437            |
| Long-term debt, less current maturities  | 1,000,000            | 2,243,768            |
| Other liabilities  | 1,407                | 75,786               |
| Stockholders' equity:  |                      |                      |
| Convertible preferred stock, issued in series, par value \$0.001; 10,000,000<br>and 65,000,000 shares authorized at 2004 and 2003, respectively;<br>61,055,286 shares issued and outstanding at 2003; liquidation preference<br>of \$146,819,436 at 2003 | -                    | 61,055               |
| Common stock, par value of \$0.001; 100,000,000 and 80,000,000 shares<br>authorized at 2004 and 2003, respectively; 27,187,042 and 1,515,150<br>shares issued at 2004 and 2003, respectively   | 27,187               | 1,515                |
| Additional paid-in capital   | 174,143,587          | 113,921,587          |
| Deferred compensation  | (671,950)            | (835,801)            |
| Treasury stock, 36,519 and 18,316 shares at 2004 and 2003, respectively  | (162,546)            | (17,750)             |
| Notes receivable from sale of stock  | (173,432)            | (448,413)            |
| Accumulated deficit  | (114,673,234)        | (87,415,765)         |
| Accumulated other comprehensive loss   | (95,144)             | -                    |
| Total stockholders' equity   | 58,394,468           | 25,266,428           |
| Total liabilities and stockholders' equity   | <u>\$ 71,187,756</u> | <u>\$ 37,323,419</u> |

See accompanying notes.

**STEREOTAXIS, INC.**

**STATEMENTS OF OPERATIONS**

|  | Year Ended December 31, |                       |                       |
|--|-------------------------|-----------------------|-----------------------|
|  | 2004                    | 2003                  | 2002                  |
| Systems revenue  | \$ 17,219,080           | \$ 3,808,036          | \$ -                  |
| Disposables, service and accessories revenue                         | 1,597,780               | 480,941               | 18,900                |
| Other revenue  | -                       | 725,900               | -                     |
| Total revenue  | 18,816,860              | 5,014,877             | 18,900                |
| Costs of revenue   | 10,672,262              | 4,051,313             | 39,760                |
| Gross profit (loss)  | 8,144,598               | 963,564               | (20,860)              |
| Operating expenses:  |                         |                       |                       |
| Research and development   | 18,437,108              | 13,886,462            | 14,742,015            |
| Sales and marketing  | 10,964,925              | 5,999,310             | 2,230,565             |
| General and administrative   | 6,315,987               | 5,028,142             | 4,528,637             |
| Total operating expenses   | 35,718,020              | 24,913,914            | 21,501,217            |
| Operating loss   | (27,573,422)            | (23,950,350)          | (21,522,077)          |
| Interest income  | 811,049                 | 375,361               | 434,470               |
| Interest expense   | (495,096)               | (461,848)             | (371,051)             |
| Net loss   | <u>\$(27,257,469)</u>   | <u>\$(24,036,837)</u> | <u>\$(21,458,658)</u> |
| Net loss per common share:   |                         |                       |                       |
| Basic and diluted  | <u>\$ (2.38)</u>        | <u>\$ (18.37)</u>     | <u>\$ (19.21)</u>     |
| Weighted average shares used in computing net loss per common share: |                         |                       |                       |
| Basic and diluted  | <u>11,470,310</u>       | <u>1,308,805</u>      | <u>1,117,301</u>      |

See accompanying notes.

# STEREOTAXIS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY

|  | Comprehensive<br>Income (Loss) | Convertible<br>Preferred Stock |          | Common Stock |         | Additional<br>Paid-In<br>Capital | Deferred<br>Compensation | Treasury<br>Stock | Notes<br>Receivable<br>From Sale<br>Of Stock | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Income (Loss) | Total<br>Stockholders'<br>Equity |
|--|--------------------------------|--------------------------------|----------|--------------|---------|----------------------------------|--------------------------|-------------------|--|------------------------|--|----------------------------------|
|  |                                | Shares                         | Amount   | Shares       | Amount  |                                  |                          |                   |  |                        |  |                                  |
| Balance at December 31, 2001   | \$ -                           | 43,488,275                     | \$43,488 | 1,261,800    | \$1,262 | \$70,837,047                     | \$(1,059,508)            | \$(2,156)         | \$(423,172)                                  | \$(41,920,270)         | \$ -   | \$ 27,476,691                    |
| Issuance of Series D-3 convertible preferred stock at \$2.17 per share, net of issuance costs of \$287,262 | -                              | 7,940,951                      | 7,941    | -            | -       | 15,352,459                       | -                        | -                 | -  | -                      | -  | 15,360,400                       |
| Exercise of stock warrants   | -                              | 205,791                        | 206      | -            | -       | 289,365                          | -                        | -                 | -  | -                      | -  | 289,571                          |
| Exercise of stock options  | -                              | -                              | -        | 128,123      | 128     | 94,210                           | -                        | -                 | -  | -                      | -  | 94,338                           |
| Notes receivable from sale of stock  | -                              | -                              | -        | -            | -       | -                                | -                        | -                 | (28,758)                                     | -                      | -  | (28,758)                         |
| Deferred compensation  | -                              | -                              | -        | -            | -       | 98,474                           | (98,474)                 | -                 | -  | -                      | -  | -                                |
| Stock-based compensation   | -                              | -                              | -        | -            | -       | -                                | 483,638                  | -                 | -  | -                      | -  | 483,638                          |
| Payments of notes receivable from sale of stock  | -                              | -                              | -        | -            | -       | -                                | -                        | -                 | 12,585                                       | -                      | -  | 12,585                           |
| Exercise of warrants to purchase common stock  | -                              | -                              | -        | -            | -       | 1,584,202                        | -                        | -                 | -  | -                      | -  | 1,584,202                        |
| Exercise of warrants to purchase convertible preferred stock in connection with long-term debt             | -                              | -                              | -        | -            | -       | 192,637                          | -                        | -                 | -  | -                      | -  | 192,637                          |
| Loss   | (21,458,658)                   | -                              | -        | -            | -       | -                                | -                        | -                 | -  | (21,458,658)           | -  | (21,458,658)                     |
| Net comprehensive income (loss):   |                                |                                |          |              |         |                                  |                          |                   |  |                        |  |                                  |
| Unrealized loss on short term investments  | -                              | -                              | -        | -            | -       | -                                | -                        | -                 | -  | -                      | -  | -                                |
| Comprehensive Loss   | \$(21,458,658)                 | -                              | -        | -            | -       | -                                | -                        | -                 | -  | -                      | -  | -                                |
| Balance at December 31, 2002   |                                | 51,635,017                     | \$51,635 | 1,389,923    | \$1,390 | \$88,448,394                     | \$ (674,344)             | \$(2,156)         | \$(439,345)                                  | \$(63,378,928)         | \$ -   | \$ 24,006,646                    |

See accompanying notes.

**STEREOTAXIS, INC.**

**STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)**

|  | Comprehensive<br>Income (Loss) | Convertible<br>Preferred Stock |          | Common Stock |         | Additional<br>Paid-In<br>Capital | Deferred<br>Compensation | Treasury<br>Stock | Notes<br>Receivable<br>From Sale<br>Of Stock | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Income (Loss) | Total<br>Stockhold<br>Equity |
|--|--------------------------------|--------------------------------|----------|--------------|---------|----------------------------------|--------------------------|-------------------|--|------------------------|--|------------------------------|
|  |                                | Shares                         | Amount   | Shares       | Amount  |                                  |                          |                   |  |                        |  |                              |
| Issuance of Series D-2 convertible preferred stock at \$2.17 per share, net of issuance costs of \$17,953  | \$ -                           | 2,764,978                      | \$ 2,765 | -            | \$ -    | \$ 5,454,716                     | \$ -                     | \$ -              | \$ -   | \$ -                   | \$ -   | \$ 5,457,000                 |
| Issuance of Series E convertible preferred stock at \$2.93 per share, net of issuance costs of \$605,106   | -                              | 3,412,970                      | 3,413    | -            | -       | 9,391,481                        | -                        | -                 | -  | -                      | -  | 9,394,000                    |
| Issuance of Series E-1 convertible preferred stock at \$2.93 per share, net of issuance costs of \$403,931 | -                              | 3,242,321                      | 3,242    | -            | -       | 9,092,827                        | -                        | -                 | -  | -                      | -  | 9,096,000                    |
| Exercise of options  | -                              | -                              | -        | 125,227      | 125     | 328,933                          | -                        | -                 | -  | -                      | -  | 329,000                      |
| Repurchase of common stock   | -                              | -                              | -        | -            | -       | -                                | -                        | (15,594)          | -  | -                      | -  | (15,594)                     |
| Interest receivable from sale of stock   | -                              | -                              | -        | -            | -       | -                                | -                        | -                 | (21,653)                                     | -                      | -  | (21,653)                     |
| Deferred compensation  | -                              | -                              | -        | -            | -       | 653,625                          | (653,625)                | -                 | -  | -                      | -  | -                            |
| Stock-based compensation   | -                              | -                              | -        | -            | -       | -                                | 492,168                  | -                 | -  | -                      | -  | 492,168                      |
| Payments from notes receivable from sale of stock  | -                              | -                              | -        | -            | -       | -                                | -                        | -                 | 12,585                                       | -                      | -  | 12,585                       |
| Issuance of warrants to purchase common stock  | -                              | -                              | -        | -            | -       | 551,611                          | -                        | -                 | -  | -                      | -  | 551,611                      |
| Net loss   | (24,036,837)                   | -                              | -        | -            | -       | -                                | -                        | -                 | -  | (24,036,837)           | -  | (24,036,837)                 |
| Other comprehensive income (loss):   |                                |                                |          |              |         |                                  |                          |                   |  |                        |  |                              |
| Unrealized loss on short term investments  | -                              | -                              | -        | -            | -       | -                                | -                        | -                 | -  | -                      | -  | -                            |
| Comprehensive Loss   | \$(24,036,837)                 | -                              | -        | -            | -       | -                                | -                        | -                 | -  | -                      | -  | -                            |
| Balance at December 31, 2003   |                                | 61,055,286                     | \$61,055 | 1,515,150    | \$1,515 | \$113,921,587                    | \$(835,801)              | \$(17,750)        | \$(448,413)                                  | \$(87,415,765)         | \$ -   | \$ 25,266,000                |

See accompanying notes.

# STEREOTAXIS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)

|   | Comprehensive<br>Income (Loss) | Convertible<br>Preferred Stock |          | Common Stock |          | Additional<br>Paid-In<br>Capital | Deferred<br>Compensation | Treasury<br>Stock | Notes<br>Receivable<br>From Sale<br>Of Stock | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Income (Loss) | Total<br>Stockholders'<br>Equity |
|---|--------------------------------|--------------------------------|----------|--------------|----------|----------------------------------|--------------------------|-------------------|--|------------------------|--|----------------------------------|
|   |                                | Shares                         | Amount   | Shares       | Amount   |                                  |                          |                   |  |                        |  |                                  |
| Balance of Series E-2 convertible<br>deferred stock at \$10.55 per<br>share, net issuance costs of<br>\$5,523                                     | \$ -                           | 3,380,830                      | \$ 5,381 | -            | \$ -     | \$ 14,087,572                    | \$ -                     | \$ -              | \$ -   | \$ -                   | \$ -   | \$ 14,092,953                    |
| Exercise of warrants to purchase<br>common stock  | -                              | -                              | -        | -            | -        | 1,603,493                        | -                        | -                 | -  | -                      | -  | 1,603,493                        |
| Amortization of stock-based<br>compensation   | -                              | -                              | -        | -            | -        | -                                | 654,501                  | -                 | -  | -                      | -  | 654,501                          |
| Payments of notes receivable<br>from sale of stock  | -                              | -                              | -        | -            | -        | -                                | -                        | -                 | 239,560                                      | -                      | -  | 239,560                          |
| Notes receivable from sale of<br>stock  | -                              | -                              | -        | -            | -        | -                                | -                        | -                 | 10,212                                       | -                      | -  | 10,212                           |
| Conversion of convertible<br>deferred stock into common<br>stock  | -                              | (66,436,116)                   | (66,436) | 19,282,324   | 19,282   | 47,154                           | -                        | -                 | -  | -                      | -  | -                                |
| Conversion of convertible<br>promissory note  | -                              | -                              | -        | 271,739      | 272      | 2,173,646                        | -                        | -                 | -  | -                      | -  | 2,173,918                        |
| Purchase of common stock  | -                              | -                              | -        | -            | -        | -                                | -                        | (144,899)         | -  | -                      | -  | (144,899)                        |
| Issuance of common stock  | -                              | -                              | -        | (13)         | -        | (103)                            | -                        | 103               | -  | -                      | -  | -                                |
| Balance of common stock upon<br>completion of initial public offering<br>and underwriter over-<br>allotment, net of issuance costs<br>\$2,919,794 | -                              | -                              | -        | 5,962,352    | 5,963    | 41,434,041                       | -                        | -                 | -  | -                      | -  | 41,440,004                       |
| Exercise of stock warrants  | -                              | -                              | -        | 20,104       | 20       | (20)                             | -                        | -                 | -  | -                      | -  | -                                |
| Exercise of stock options   | -                              | -                              | -        | 135,386      | 135      | 385,567                          | -                        | -                 | -  | -                      | -  | 385,702                          |
| Payments of interest on notes<br>receivable   | -                              | -                              | -        | -            | -        | -                                | -                        | -                 | 25,209                                       | -                      | -  | 25,209                           |
| Stock-based compensation  | -                              | -                              | -        | -            | -        | 490,650                          | (490,650)                | -                 | -  | -                      | -  | -                                |
| Loss  | (27,257,469)                   | -                              | -        | -            | -        | -                                | -                        | -                 | -  | (27,257,469)           | -  | (27,257,469)                     |
| Other comprehensive income<br>(loss)  | -                              | -                              | -        | -            | -        | -                                | -                        | -                 | -  | -                      | -  | -                                |
| Realized loss on short term<br>investments  | (95,144)                       | -                              | -        | -            | -        | -                                | -                        | -                 | -  | -                      | (95,144)   | (95,144)                         |
| Comprehensive Loss  | <u>\$(27,352,613)</u>          | -                              | -        | -            | -        | -                                | -                        | -                 | -  | -                      | -  | -                                |
| Balance at December 31, 2004  |                                | - \$ -                         | -        | 27,187,042   | \$27,187 | \$174,143,587                    | \$(671,950)              | \$(162,546)       | (173,432)                                    | \$(114,673,234)        | \$(95,144)   | \$ 58,394,468                    |

See accompanying notes.

**STEREOTAXIS, INC.**  
**STATEMENTS OF CASH FLOWS**

|   | 2004                 | Year Ended December 31,<br>2003 | 2002                 |
|---|----------------------|---------------------------------|----------------------|
| <b>Cash flows from operating activities</b>                                   |                      |                                 |                      |
| Net loss  | \$(27,257,469)       | \$(24,036,837)                  | \$(21,458,658)       |
| Adjustments to reconcile net loss to cash used in operating activities:       |                      |                                 |                      |
| Depreciation  | 754,710              | 447,786                         | 406,766              |
| Amortization  | 133,333              | 55,556                          | -                    |
| Stock-based compensation  | 452,130              | 492,168                         | 483,638              |
| Loss on asset disposal  | 42,425               | -                               | -                    |
| Changes in operating assets and liabilities:                                  |                      |                                 |                      |
| Accounts receivable   | (8,061,484)          | (123,575)                       | (80,550)             |
| Notes receivable  | 114,939              | (621,324)                       | -                    |
| Inventories   | (243,766)            | (2,069,621)                     | (2,360,607)          |
| Prepaid expenses and other current assets                                     | (1,272,409)          | (405,987)                       | (368,106)            |
| Other assets  | (19,338)             | 18,778                          | (77,337)             |
| Accounts payable  | 431,976              | 192,136                         | 169,638              |
| Accrued liabilities   | 773,983              | 2,379,901                       | 468,440              |
| Deferred revenue  | 2,227,365            | (837,607)                       | 826,000              |
| Other   | 109,735              | 39,232                          | (38,159)             |
| Net cash used in operating activities   | (31,813,870)         | (24,469,394)                    | (22,028,935)         |
| <b>Cash flows from investing activities</b>                                   |                      |                                 |                      |
| Sale of equipment   | 1,489,904            | -                               | -                    |
| Purchase/disposal of equipment  | (1,535,420)          | (2,057,671)                     | (308,512)            |
| Sale of available-for-sale investments  | 6,936,710            | -                               | 1,788,105            |
| Purchase of available-for-sale investments                                    | (36,545,431)         | (5,124,365)                     | -                    |
| Net cash (used in) provided by investing activities                           | (29,654,237)         | (7,182,036)                     | 1,479,593            |
| <b>Cash flows from financing activities</b>                                   |                      |                                 |                      |
| Proceeds from long-term debt  | 2,000,000            | 1,829,690                       | 3,874,627            |
| Payments under long-term debt   | (2,622,647)          | (2,482,240)                     | (688,995)            |
| Proceeds from issuance of stock and warrants, net of issuance costs           | 57,522,153           | 24,829,113                      | 17,521,148           |
| Purchase of treasury stock  | (90)                 | (15,594)                        | -                    |
| Payments received on notes receivable from sale of common stock               | 119,960              | 12,585                          | 12,585               |
| Net cash provided by financing activities                                     | 57,019,376           | 24,173,554                      | 20,719,365           |
| Net increase (decrease) in cash and cash equivalents                          | (4,448,731)          | (7,477,876)                     | 170,023              |
| Cash and cash equivalents at beginning of period                              | 21,356,247           | 28,834,123                      | 28,664,100           |
| Cash and cash equivalents at end of period                                    | <u>\$ 16,907,516</u> | <u>\$ 21,356,247</u>            | <u>\$ 28,834,123</u> |
| Supplemental disclosures of cash flow information:                            |                      |                                 |                      |
| Noncash items:  |                      |                                 |                      |
| Acquisition of purchased technology upon issuance of convertible note payable | \$ -                 | \$ 2,000,000                    | \$ -                 |
| Conversion of note payable and accrued interest to common stock               | <u>\$ 2,173,918</u>  | <u>\$ -</u>                     | <u>\$ -</u>          |
| Acquisition of treasury shares in lieu of payment of notes receivable         | <u>\$ 144,809</u>    | <u>\$ -</u>                     | <u>\$ -</u>          |
| Interest paid   | <u>\$ 422,085</u>    | <u>\$ 394,287</u>               | <u>\$ 371,051</u>    |

See accompanying notes.

## Notes to Financial Statements

### 1. Description of Business

Stereotaxis, Inc. (the Company) designs, manufactures, and markets an advanced cardiology instrument control system for the interventional treatment of coronary artery disease and arrhythmias. The Company also markets and sells various disposable interventional devices, including catheters, guidewires and stent delivery devices, for use in conjunction with its system. By 2003, the Company had received U.S. and European regulatory approval for the core components of its system.

Prior to 2003, the Company's principal activities involved obtaining capital, business development, performing research and development activities, and funding prototype development. As such, the Company was classified as a development-stage company from its inception on June 13, 1990 through December 31, 2002. During 2003, the Company emerged from the development-stage and began to generate revenue from the commercial launch of its systems.

### 2. Summary of Significant Accounting Policies

#### *Cash and Cash Equivalents*

The Company considers all short-term deposits purchased with original maturities of three months or less to be cash equivalents. The Company places its cash with high-credit-quality financial institutions and invests primarily in money market accounts.

#### *Investments*

In accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, the Company's investment securities are classified as available-for-sale and are carried at market value, which approximates cost. Realized gains or losses, calculated based on the specific identification method, were not material for the years ended December 31, 2004, 2003 and 2002. Interest and dividends on securities classified as available-for-sale are included in interest income.

#### *Accounts Receivable and Allowance for Uncollectible Accounts*

Accounts receivable primarily include amounts due from hospitals and medical centers for acquisition of magnetic systems and associated disposable device sales. Credit is granted on a limited basis, with most balances due within 30 days of billing. The provision for bad debts is based upon management's assessment of historical and expected net collections considering business and economic conditions and other collection indicators.

#### *Financial Instruments*

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and long-term debt. The carrying value of such amounts reported at the applicable balance sheet dates approximates fair value.

#### *Inventory*

The Company values its inventory at the lower of cost, as determined using the first-in, first-out (FIFO) method, or market. The Company periodically reviews its physical inventory for obsolete items and provides a reserve upon identification of potential obsolete items.

### ***Property and Equipment***

Property and equipment consist primarily of laboratory, office, and computer equipment and leasehold improvements and are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives or life of the base lease term, ranging from one to five years.

### ***Long-Lived Assets***

If facts and circumstances suggest that a long-lived asset may be impaired, the carrying value is reviewed. If this review indicates that the carrying value of the asset will not be recovered, as determined based on projected undiscounted cash flows related to the asset over its remaining life, the carrying value of the asset is reduced to its estimated fair value.

### ***Intangible Assets***

Intangible assets consist of purchased technology arising out of collaboration with a strategic investor valued at the cost of acquisition on the acquisition date and amortized over its estimated useful life of 15 years. Accumulated amortization at December 31, 2004 and 2003 is \$188,889 and \$55,556, respectively. Amortization expense in 2004 and 2003 is \$133,333 and \$55,556, respectively, as determined under the straight-line method. The estimated future amortization of intangible assets is \$133,333 annually through June 2019.

### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and loss during the reporting period. Actual results could differ from those estimates.

### ***Revenue and Costs of Revenue***

The Company recognizes systems revenue from system sales made directly to end users upon installation, provided there are no uncertainties regarding acceptance, persuasive evidence of an arrangement exists, the sales price is fixed or determinable, and collection of the related receivable is reasonably ensured. When installation is required for revenue recognition, the determination of acceptance is made by the Company's employees based on criteria set forth in the terms of the sale. Revenue from system sales made to distributors is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. If uncertainties exist regarding collectability, the Company recognizes revenue when those uncertainties are resolved. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Co-placement fees from strategic partners for the Company's collaboration in certain sales and marketing efforts will be recognized as revenue when earned under the terms of the respective agreements. Revenue from services, whether sold individually or as a separable unit of accounting in a multi-element arrangement, is deferred and amortized over the service period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. The Company recognizes revenue from disposable device sales or accessories upon shipment, and an appropriate reserve for returns is established. Other revenue represents a system sale for which the cost of production was charged to research and development costs in 2002 and 2001.

Costs of revenue include direct product costs, installation labor, estimated warranty costs, and training and product maintenance costs. The Company also includes in cost of revenue any expected loss related to executed contracts in the period in which the loss becomes known. In the years ended December 31, 2004, 2003 and 2002, the



Company incurred \$103,494, \$278,320 and \$33,580, respectively, for costs in excess of contractual revenues, primarily on certain system sales.

### ***Research and Development Costs***

Internal research and development costs, including clinical and regulatory costs incurred prior to receiving Food and Drug Administration approval, are expensed in the period incurred. Directed research performed by hospitals (which, at times, may also be customers) at the Company's request are expensed in the period such services are provided. Amounts paid for directed research were \$481,949, \$128,424, and \$100,041 in 2004, 2003, and 2002, respectively. Amounts receivable from strategic partners under research reimbursement agreements are recorded as a contra-research and development expense in the period reimbursable costs are incurred. Advance receipts or other unearned reimbursements are included in accrued liabilities on the accompanying balance sheet until earned.

### ***Stock-Based Compensation***

As permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, the Company has elected to follow Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for stock-based employee compensation. Under APB No. 25, if the exercise price of the Company's employee and director stock options equals or exceeds the estimated fair value of the underlying stock on the date of grant and the number of options is not variable, no compensation expense is recognized. Options are variable if the options are forfeitable when performance milestones described in the option agreements may not occur. When the exercise price of the employee or director stock options is less than the estimated fair value of the underlying stock (intrinsic value) at the date of grant or for variable options through the vesting or forfeiture date, the Company records deferred compensation for the intrinsic value and amortizes the amount to expense over the service period on a straight-line basis. Deferred compensation for variable options granted to employees and directors is periodically remeasured through the vesting or forfeiture date.

Stock options issued to nonemployees, including individuals for scientific advisory services, are recorded at their fair value as determined in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services*, and recognized over the service period. Deferred compensation for options granted to nonemployees is periodically remeasured through the vesting or forfeiture date.

The following table illustrates the effect on net loss if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

|   | Year Ended December 31, |                       |                       |
|---|-------------------------|-----------------------|-----------------------|
|   | 2004                    | 2003                  | 2002                  |
| Net loss, as reported   | \$(27,257,469)          | \$(24,036,837)        | \$(21,458,658)        |
| Add total stock-based compensation cost included in net loss          | 452,130                 | 492,168               | 483,638               |
| Deduct total stock-based compensation expense under fair value method | (2,873,162)             | (1,793,447)           | (1,104,659)           |
| Pro forma net loss  | <u>\$(29,678,501)</u>   | <u>\$(25,338,116)</u> | <u>\$(22,079,679)</u> |
| Net loss per share, basic and diluted, as reported                    | \$ (2.38)               | \$ (18.37)            | \$ (19.21)            |
| Net loss per share, basic and diluted, pro forma                      | \$ (2.59)               | \$ (19.36)            | \$ (19.76)            |

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for the years ended 2004, 2003 and 2002: dividend yield of 0%, expected volatility ranging from 70% to 120%, risk-free interest rates ranging from 1.09% to 5.28%, and an initial expected life ranging from six to ten years. The weighted average fair value of the options at grant date was \$7.49, \$5.94, and \$4.75, for 2004, 2003 and 2002, respectively. Future pro forma results of operations may be materially different from amounts reported, as future years will include the effects of additional stock option grants.

Option valuation models require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models may not accurately reflect the fair value of employee stock options.

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), "Share-Based Payment". SFAS No. 123(R) supersedes APB Opinion No. 25 and requires recognition of an expense when goods or services are provided. SFAS No. 123(R) requires the determination of the fair value of the share-based compensation at the grant date and the recognition of the related expense over the period in which the share-based compensation vests. The Company intends to adopt the provisions of SFAS No. 123(R) effective July 1, 2005. These new accounting rules will lead to a decrease in reported earnings and the Company has not yet determined the exact impact SFAS No. 123(R) will have on its financial statements.

### ***Net Loss per Share***

Basic loss per common share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share is computed by dividing the loss for the period by the weighted average number of common and common equivalent shares outstanding during the period.

The Company has excluded all preferred stock, outstanding options and warrants, and shares subject to repurchase from the calculation of diluted loss per common share because all such securities are antidilutive for all periods presented.

### ***Income Taxes***

In accordance with SFAS No. 109, *Accounting for Income Taxes*, a deferred income tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred income tax assets unless, based upon available evidence, it is more likely than not the deferred income tax assets will be realized.

### ***Patent Costs***

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain.

### ***Concentrations of Risk***

The majority of the company's cash, cash equivalents and investments are deposited with one major financial institution in the United States of America. Deposits in this institution exceed the amount of insurance provided on such deposits.

One customer, Siemens, accounted for \$3,996,568, or 21%, of total net sales for the year ended December 31, 2004. We did not have one customer accounting for 10% or more of our total net sales for the year ended December 31, 2003.

### ***Comprehensive Income (Loss)***

Comprehensive income (loss) generally represents all changes in stockholders' equity except those resulting from investments by stockholders, and includes the Company's unrealized losses on marketable securities of \$95,144 at December 31, 2004.

### ***Reclassifications***

Certain amounts in the prior year financial statements have been reclassified to conform to current year presentation.

### 3. Investments

The following table summarizes available-for-sale securities included in short and long-term investments as of the respective dates:

|                              | <u>December 31, 2004</u> |                   |               |                   | <u>December 31, 2003</u> |                   |               |                   |
|------------------------------|--------------------------|-------------------|---------------|-------------------|--------------------------|-------------------|---------------|-------------------|
|                              | <u>Cost</u>              | <u>Unrealized</u> |               | <u>Fair Value</u> | <u>Cost</u>              | <u>Unrealized</u> |               | <u>Fair Value</u> |
|                              |                          | <u>Gains</u>      | <u>Losses</u> |                   |                          | <u>Gains</u>      | <u>Losses</u> |                   |
| Short-term investments:      |                          |                   |               |                   |                          |                   |               |                   |
| Corporate debt               | \$ 6,895,637             | \$ -              | \$(276,708)   | \$ 6,618,929      | \$5,124,365              | \$ -              | \$ -          | \$5,124,365       |
| U.S. government agency       | 12,044,291               | 102,617           | -             | 12,146,908        | -                        | -                 | -             | -                 |
| Commercial paper             | 9,838,684                | 136,797           | -             | 9,975,481         | -                        | -                 | -             | -                 |
| Total short-term investments | 28,778,612               | 239,414           | (276,708)     | 28,741,318        | 5,124,365                | -                 | -             | 5,124,365         |
| Long-term investments:       |                          |                   |               |                   |                          |                   |               |                   |
| Corporate debt               | 1,919,737                | -                 | (42,876)      | 1,876,861         | -                        | -                 | -             | -                 |
| U.S. government agency       | 4,034,738                | 1,088             | (16,062)      | 4,019,764         | -                        | -                 | -             | -                 |
| Total long-term investments  | 5,954,475                | 1,088             | (58,938)      | 5,896,625         | -                        | -                 | -             | -                 |
| Total                        | \$34,733,087             | \$240,502         | \$(335,646)   | \$34,637,943      | \$5,124,365              | \$ -              | \$ -          | \$5,124,365       |

The Company views its available-for-sale portfolio as available for use in its current operations. The following is a summary of the cost and estimated fair value of available-for-sale securities at December 31, 2004, by maturity date:

|                            | <u>2004</u>         |                     |
|----------------------------|---------------------|---------------------|
|                            | <u>Cost</u>         | <u>Fair Value</u>   |
| Mature in less than 1 year | \$28,778,612        | \$28,741,318        |
| Mature in one year         | 5,954,475           | 5,896,625           |
| Total                      | <u>\$34,733,087</u> | <u>\$34,637,943</u> |

#### 4. Inventory

Inventory consists of:

|                          | December 31,        |                     |
|--------------------------|---------------------|---------------------|
|                          | 2004                | 2003                |
| Raw Materials            | \$ 1,401,591        | \$ 975,052          |
| Work in Process          | 498,174             | 487,344             |
| Finished Goods           | 2,886,984           | 3,073,584           |
| Reserve for obsolescence | (112,755)           | (105,752)           |
|                          | <u>\$ 4,673,994</u> | <u>\$ 4,430,228</u> |

#### 5. Property and Equipment

Property and equipment consist of the following:

|                               | December 31,        |                     |
|-------------------------------|---------------------|---------------------|
|                               | 2004                | 2003                |
| Equipment                     | \$ 2,972,314        | \$ 1,806,186        |
| Equipment held for lease      | -                   | 1,533,094           |
| Leasehold improvements        | 380,062             | 309,213             |
|                               | <u>3,352,376</u>    | <u>3,648,493</u>    |
| Less accumulated depreciation | <u>1,794,529</u>    | <u>1,339,026</u>    |
|                               | <u>\$ 1,557,847</u> | <u>\$ 2,309,467</u> |

Equipment held for lease at December 31, 2003 consisted of medical devices provided to customers under a prepaid operating lease arrangements, whereby the Company was the lessor. Amounts prepaid under the five-year operating leases are included in deferred revenue until earned over the term of the lease. During 2004, the Company sold all equipment held for lease. Depreciation expense for the years ended December 31, 2004, 2003 and 2002 is \$628,725, \$447,786, and \$406,766, respectively.

#### 6. Related Party Transactions

In the normal course of business, the Company has entered into an agreement with Biosense Webster, Inc., a subsidiary of Johnson and Johnson and an investor, under which the Company jointly develops integrated systems and certain disposable interventional devices. Amounts paid to this investor under this agreement totaled \$3,417,522 and \$972,190 in 2004 and 2003, respectively. In addition, the Company is entitled to receive royalty payments from the investor based on a profit formula pertaining to sales of certain disposable devices. The Company has not received any royalty payments to date under this agreement. In the event that the Company elects to terminate this agreement in certain specified change of control situations, the strategic investor would be entitled to a termination payment of 5% of the total equity value of the Company in the change of control transaction up to a maximum of \$10 million.

## 7. Accrued Liabilities

Accrued liabilities consist of the following:

|   | December 31,       |                    |
|---|--------------------|--------------------|
|   | 2004               | 2003               |
| Accrued salaries, bonus, and benefits     | \$2,006,700        | \$1,570,063        |
| Accrued research and development          | 1,446,201          | 727,143            |
| Accrued legal and other professional fees | 623,411            | 968,532            |
| Other                                     | 1,633,904          | 1,670,495          |
|   | <u>\$5,710,216</u> | <u>\$4,936,233</u> |

## 8. Long-Term Debt

Long-term debt consists of the following:

|   | December 31,       |                    |
|---|--------------------|--------------------|
|   | 2004               | 2003               |
| Revolving credit agreement, due June 2006 | \$ -               | \$1,250,000        |
| Term note, due December 2004              | -                  | 711,469            |
| Term note, due September 2005             | 243,768            | 571,613            |
| Term note, due June 2007                  | 1,666,666          | -                  |
| Pay-in-kind note, due August 2006         | -                  | 2,000,000          |
|   | <u>1,910,434</u>   | <u>4,533,082</u>   |
| Less current maturities                   | <u>910,434</u>     | <u>2,289,314</u>   |
|   | <u>\$1,000,000</u> | <u>\$2,243,768</u> |

In January 2002, the Company entered into a term note due in December 2004 with its primary lender for \$2,000,000 (January 2002 term note). In conjunction with the January 2002 term note, the Company issued its primary lender warrants to purchase 14,081 shares of Company's common stock at a price per share of \$7.81. The total proceeds under the January 2002 term note of \$2,000,000 were allocated between the term note and the warrants based on an estimate of each security's fair value at the date of issuance. Under the January 2002 term note, the Company was required to make equal payments of principal and interest, at 10%, through December 2004 plus a final payment of 4% of the original note.

The warrants expire after five years and can be exercised at any time. The fair value assigned to the warrants of \$92,793 was reflected in additional paid-in capital on the balance sheet and amortized to interest expense over the life of the January 2002 term note. Fair value was determined utilizing the Black-Scholes valuation method, assuming a volatility of 120%, a risk-free interest rate of 3% and an expected life of five years.

In March 2002, the Company entered into a revolving line of credit agreement (Revolving Credit Agreement) with a maximum borrowing capacity of \$2,000,000, limited to the value of qualifying receivable and inventory balances, with its primary lender. In conjunction with the Revolving Credit Agreement, the Company issued its primary lender warrants to purchase 10,241 shares of the Company's common stock at a price per share of \$7.81. The Revolving Credit Agreement was amended in July 2003 to increase the maximum borrowing capacity to \$3,000,000, and in April 2004 to increase the maximum borrowing capacity to \$8,000,000. Borrowings under the Revolving Credit Agreement are subject to monthly interest at the lender's prime rate plus 1.25%, subject to a minimum interest rate of

5.25%, and are due in full in April 2006. The Company is required to maintain a ratio of "quick" assets (cash, cash equivalents, accounts receivable and short term investments) to current liabilities (less deferred revenue) of at least 1.5 to 1. In November, 2004, the Agreement was amended to require that the Company maintain a minimum tangible net worth of at least \$30.0 million. Remaining available borrowing capacity at December 31, 2004 is \$8,000,000.

The warrants issued in conjunction with the Revolving Credit Agreement expire after five years and can be exercised at any time. The fair value assigned to the warrants of \$67,264 is reflected in additional paid-in capital on the balance sheet and amortized to interest expense over the 12-month life of the Revolving Credit Agreement. Fair value was determined utilizing the Black-Scholes valuation method, assuming a volatility of 120%, a risk-free interest rate of 3% and an expected life of five years.

In October 2002, the Company entered into a term note due in September 2005 with its primary lender for \$1,000,000 (October 2002 term note). In conjunction with the October 2002 term note, the Company issued its primary lender warrants to purchase 5,000 shares of the Company's common stock at a price per share of \$7.81. The total proceeds under the October 2002 term note of \$1,000,000 were allocated between the term note and the warrants based on an estimate of each security's fair value at the date of issuance. Under the October 2002 term note, the Company is required to make equal payments of principal and interest, at 10%, through September 2005 plus a final payment of 3% of the original note.

The warrants expire after five years and can be exercised at any time. The fair value assigned to the warrants of \$32,580 was reflected in additional paid-in capital on the balance sheet and amortized to interest expense over the life of the October 2002 term note. Fair value was determined utilizing the Black-Scholes valuation method, assuming a volatility of 120%, a risk-free interest rate of 3% and an expected life of five years.

In April 2004, the Company entered into a term note due in June 2007 with its primary lender for \$2,000,000, which was drawn down in June 2004 (April 2004 term note). The Company is required to make equal payments of principal and interest, at 7%, through June 2007.

The January 2002 term note, Revolving Credit Agreement, October 2002 term note and April 2004 term note (collectively, the Credit Agreements) are secured by substantially all of the Company's assets. The Credit Agreements also include certain equity level covenants and require the Company to maintain minimum liquidity levels. The Company is also required under the Credit Agreements to maintain its primary operating account and the majority of its cash and investment balances in accounts with the primary lender.

In August 2003, the Company issued a \$2,000,000 cumulative convertible pay-in-kind 8%, three-year note to a strategic partner pursuant to an agreement between the parties to transfer certain purchased technology to the Company, which is treated as a noncash activity in the accompanying statement of cash flows. The balance of the note, including accrued and unpaid interest, was automatically converted into shares of common stock immediately prior to the closing of the initial public offering of the Company's common stock at a conversion price equal to the gross per share proceeds to such offering, prior to deduction of underwriting commissions and discounts. As of December 31, 2003, \$67,561 of interest was accrued on this note. Upon the closing of the Company's initial public offering of its stock in August 2004, this note was converted into 271,739 shares of common stock.

Contractual principal maturities of long-term debt at December 31, 2004 are as follows:

|      |                    |
|------|--------------------|
| 2005 | \$ 910,434         |
| 2006 | 666,667            |
| 2007 | <u>333,333</u>     |
|      | <u>\$1,910,434</u> |

## 9. Lease Obligations

The Company leases its facilities under operating leases. For the years ended December 31, 2004, 2003, and 2002 rent expense was \$857,533, \$660,901, and \$569,079, respectively.

In November 2004, the Company entered into an office lease agreement under which the Company will lease space in a new building. The Company intends to move its current headquarters to the new facilities in St. Louis, MO. The escalating lease is effective December 1, 2005 and has a term of ten years.

The future minimum lease payments under noncancelable leases as of December 31, 2004 are as follows:

| <u>Year</u>                  | <u>Operating<br/>Lease</u> |
|------------------------------|----------------------------|
| 2005                         | \$ 792,239                 |
| 2006                         | 784,992                    |
| 2007                         | 707,561                    |
| 2008                         | 747,766                    |
| 2009                         | 890,272                    |
| Beyond 2009                  | <u>6,550,023</u>           |
| Total minimum lease payments | <u>\$10,472,853</u>        |

## 10. Stockholders' Equity

### *Initial Public Offering*

On August 12, 2004, the Company completed an initial public offering in which it sold 5,500,000 shares of its common stock at \$8.00 per share for proceeds of approximately \$38.0 million, net of underwriting discounts and other offering costs. Upon the closing of the offering, all of the Company's outstanding shares of convertible preferred stock converted into 19,282,325 shares of common stock including 827,953 shares issued as a result of anti-dilution provisions with respect to certain series of our preferred stock. On September 3, 2004, the underwriters exercised an over-allotment option to purchase an additional 462,352 shares, resulting in net cash proceeds of approximately \$3.4 million.

### *Common Stock*

In July 2004 the Company completed a 1-for-3.6 reverse stock split affecting all of its outstanding shares of common stock. As a result of this split, the conversion ratio of our convertible preferred stock into common stock was adjusted accordingly. Upon the closing of the initial public offering of the Company's stock all of the shares of preferred stock automatically converted into shares of common stock.

The holders of common stock are entitled one vote for each share held and to receive dividends whenever funds are legally available and when declared by the Board of Directors subject to the prior rights of holders of all classes of stock having priority rights as dividends. No dividends have been declared or paid as of December 31, 2004.



The Company has reserved shares of common stock for the exercise of warrants, the issuance of options granted under the Company's stock option plan and its stock purchase plan as follows:

|                              | <b>December 31,</b> |                   |
|------------------------------|---------------------|-------------------|
|                              | <b>2004</b>         | <b>2003</b>       |
| Convertible preferred stock  | -                   | 16,959,801        |
| Warrants                     | 1,135,526           | 894,204           |
| Stock option plan            | 2,439,765           | 1,975,265         |
| Employee Stock Purchase Plan | 277,777             | -                 |
|                              | <u>3,853,068</u>    | <u>19,829,270</u> |

The Company has outstanding shares of common stock that are subject to the Company's right to repurchase at the original issuance price upon the occurrence of certain events as defined in the agreements related to the sale of such stock. As of December 31, 2004 and 2003, shares subject to repurchase were 8,681 and 55,497, respectively.

### ***Convertible Preferred Stock***

Upon the closing of the Company's initial public offering in August 2004, all of the outstanding shares of convertible preferred stock converted into 19,282,325 shares of common stock

As of December 31, 2003, the Company had convertible preferred stock outstanding as follows:

| <b>Date Issued</b>          | <b>Series</b> | <b>Price Paid<br/>Per Share</b> | <b>Number of Shares</b> | <b>Liquidation Value<br/>December 31, 2003</b> |
|-----------------------------|---------------|---------------------------------|-------------------------|--|
| December 1990               | A             | \$0.50                          | 400,000                 | \$ 461,667                                     |
| April 1993                  | A             | 0.45                            | 2,222,222               | 2,216,666                                      |
| September 1994              | A             | 1.00                            | 50,000                  | 49,875   |
| December 1994               | B             | 0.72                            | 4,139,117               | 5,611,952                                      |
| April 1995                  | B             | 0.72                            | 520,833                 | 669,705  |
| November 1996-February 1997 | B             | 0.72                            | 2,352,949               | 2,860,793                                      |
| June-December 1998          | C             | 1.50                            | 11,999,987              | 27,737,470                                     |
| April 2000                  | D             | 2.17                            | 11,751,147              | 34,849,985                                     |
| November-December 2001      | D-1           | 2.17                            | 10,052,020              | 26,357,234                                     |
| October 2002                | C             | 1.50                            | 205,791                 | 345,986  |
| December 2002               | D-2           | 2.17                            | 7,940,950               | 19,026,849                                     |
| January 2003                | D-2           | 2.17                            | 2,764,979               | 6,550,002                                      |
| June 2003                   | E             | 2.93                            | 3,412,970               | 10,541,668                                     |
| December 2003               | E-1           | 2.93                            | 3,242,321               | 9,539,584                                      |
|                             |               |                                 | <u>61,055,286</u>       | <u>\$146,819,436</u>                           |

As a result of our reverse 1-for-3.6 common stock split in July 2004, the conversion ratio for preferred shares into common shares was automatically adjusted accordingly.

Prior to the conversion of preferred stock to common stock in conjunction with our initial public offering in August 2004, preferred stockholders were entitled to cumulative dividends at the rate of \$0.05, \$0.07, \$0.15, \$0.217, \$0.217, \$0.217, \$0.293, \$0.293, and \$0.293 per share per annum (post split basis) on each outstanding share of Series A, B, C, D, D-1, D-2, E, E-1, and E-2 preferred stock as adjusted for stock splits and recapitalizations, if declared by the Board of Directors, payable in preference to common stock dividends. No dividends have been declared or paid by the Company.

Prior to the conversion of preferred stock to common stock in conjunction with our initial public offering in August 2004, preferred shareholders were entitled to certain liquidation preferences. Preferred shares' liquidation value equaled the original purchase price plus amounts equal to all dividends in arrears. Cumulative dividends in arrears totaled \$0 and \$32,171,521 at December 31, 2004 and 2003, respectively; however, as mentioned above, no dividends have been declared. Prior to the conversion of preferred stock into common stock, holders of common stock were entitled to their pro-rata share of the assets of the Company after liquidation payments were made to the preferred stockholders. As of December 31, 2004, all of the Company's preferred shares had been converted to common shares.

### ***Notes Receivable***

At December 31, 2004 and 2003, an officer of the Company, consultants, members of the Board of Directors, and employees have outstanding promissory notes including accrued and unpaid interest totaling \$173,432 and \$448,413, respectively, related to the sale of common stock to such individuals. The notes are full-recourse and are also secured by the underlying stock. These notes bear interest at a range from 4.5% to 8.0% per annum and are due from 2005 through 2006. These notes receivable are reflected on the balance sheets as a component of stockholders' equity.

### ***Stock Option Plans***

In 2002, the Board of Directors adopted a stock incentive plan (the 2002 Stock Incentive Plan) and a nonemployee directors' stock plan (2002 Director Plan). In 1994, the Board of Directors adopted the 1994 Stock Option Plan. At December 31, 2004 and 2003, the Board of Directors has reserved a total of 2,439,765 and 1,975,265 respectively, shares of the Company's common stock to provide for current and future grants under the 2002 Stock Incentive Plan and the 2002 Director Plan and for all current grants under the 1994 Stock Option Plan. In 2002, the Board of Directors adopted a provision providing for an annual increase in the number of shares reserved for stock options of the lesser of 3.25% of outstanding common shares or 833,333 shares, on January 1 of each year through January 1, 2007.

The 2002 Stock Incentive Plan allows for the grant of incentive stock options and non-qualified stock options to employees, Board members, and consultants. Options granted under the 2002 Stock Incentive Plan expire no later than ten years from the date of grant. The exercise price of each incentive stock option shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. The exercise price of each non-qualified option shall not be less than 85% of the fair value of the stock subject to the option on the date the option is granted. The vesting provisions of individual options may vary, but incentive stock options generally vest 25% on the first anniversary of each grant and 1/48 per month over the next three years. Non-qualified stock options generally vest ratably over a period of two to four years.

The 2002 Director Plan allows for the grant of non-qualified stock options to the Company's nonemployee directors. Options granted under the 2002 Director Plan expire no later than ten years from the date of grant. The exercise price of options under the 2002 Director Plan shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. The options generally vest 100% on the first anniversary of each grant.

The 1994 Stock Option Plan allows for the grant of incentive stock options and non-qualified stock options to employees, Board members, and consultants to the Company. Options granted under the 1994 Stock Option Plan expire no later than ten years from the date of grant. The exercise price of each incentive stock option shall be not less than 100% of the fair value of the stock subject to the option on the date the option is granted. The exercise price of each non-qualified option shall be not less than 85% of the fair value of the stock subject to the option on the date the option is granted. The vesting provisions of individual options may vary but in each case will provide for vesting of at least 20% of the total number of shares subject to the option per year. Options granted may be exercised prior to

vesting, in which case the related shares would be subject to repurchase by the Company at original purchase price until vested. In February 2002, the Compensation Committee of the Board of Directors resolved to remove any performance or milestone related provisions of certain stock option arrangements. The intrinsic value of these options related to the unvested portion of these options is being amortized to compensation expense over the remaining vesting period. In addition, in February 2002, the Board accelerated vesting on certain stock options granted to certain advisors to the Company and to nonemployee Board members.

As of December 31, 2004, 2003, and 2002, 1,362,239, 683,906, and 237,077 options were vested and outstanding under all stock plans, respectively.

A summary of the options outstanding is as follows:

|                                | <b>Number of<br/>Shares</b> | <b>Range of<br/>Exercise Price</b> | <b>Weighted<br/>Average Price<br/>per Share</b> |
|--------------------------------|-----------------------------|------------------------------------|---|
| Outstanding, December 31, 2001 | 746,219                     | \$0.14-\$1.62                      | \$1.14  |
| Granted                        | 775,694                     | \$4.75-\$5.94                      | \$4.96  |
| Exercised                      | (128,123)                   | \$0.25-\$1.62                      | \$2.39  |
| Forfeited                      | <u>(103,268)</u>            | \$0.54-\$5.94                      | \$0.72  |
| Outstanding, December 31, 2002 | 1,290,522                   | \$0.14-\$5.94                      | \$3.35  |
| Granted                        | 635,972                     | \$5.94                             | \$5.94  |
| Repurchased                    | 14,323                      | \$1.08-\$1.37                      | \$1.09  |
| Exercised                      | (125,227)                   | \$0.25-\$5.94                      | \$2.57  |
| Forfeited                      | <u>(139,370)</u>            | \$0.54-\$5.94                      | \$4.33  |
| Outstanding, December 31, 2003 | 1,676,220                   | \$0.25-\$5.94                      | \$4.29  |
| Granted                        | 935,553                     | \$4.75-\$11.54                     | \$7.49  |
| Repurchased                    | 115                         | \$0.78                             | \$0.78  |
| Exercised                      | (135,387)                   | \$0.25-\$5.94                      | \$2.84  |
| Forfeited                      | <u>(223,331)</u>            | \$0.54-\$7.02                      | \$6.33  |
| Outstanding, December 31, 2004 | <u>2,253,170</u>            | \$0.25-\$11.54                     | \$5.50  |

As of December 31, 2004 and 2003, the weighted average remaining contractual life of the options outstanding was 8.1 years and 8.0 years, respectively.

### Deferred Compensation

For the years ended December 31, 2004, 2003, and 2002, the Company recorded stock-based compensation expense related primarily to grants of non-qualified options to consultants and other nonemployees of \$452,130, \$492,168, and \$483,638, respectively. As further described in Note 2, the Company records stock-based compensation expense to non-employees under EITF No. 96-18 based on the fair value of the equity instrument issued as determined using the Black-Scholes valuation method. As of December 31, 2004, deferred compensation of \$671,950 is expected to be expensed over the term of the underlying options in future years as follows:

|       |                  |
|-------|------------------|
| 2005  | \$422,574        |
| 2006  | 223,135          |
| 2007  | <u>26,241</u>    |
| Total | <u>\$671,950</u> |

Deferred compensation is recorded as a separate component of stockholders' equity. As of December 31, 2004 and 2003, \$610,093 and \$688,851, respectively, of deferred compensation is subject to periodic remeasurement.

In 2003, the Company recognized additional deferred compensation of \$360,297 related to modification of an option grant to allow an employee to retain and continue to vest in outstanding options upon change to nonemployee status.

### **Warrants**

As of December 31, 2004, the Company has issued warrants to purchase 418,819 shares of common stock at \$7.81 per share exercisable through December 2006, warrants to purchase 446,063 shares of common stock at \$7.81 exercisable through December 2007 and warrants to purchase 298,936 shares of common stock at \$10.55 per share exercisable through February 2009. All such warrants were issued in connection with a corresponding issuance of convertible preferred stock and were credited to additional paid-in capital at their fair value with a corresponding reduction to preferred offering proceeds. During 2004, warrants for 57,604 were exercised under a cashless exercise provision of the warrant agreements for a net issuance of 20,104 shares of common stock.

Additionally, in connection with closing its credit agreements in 2002, the Company issued to its primary lender warrants to purchase 29,322 shares of its common stock at \$7.81 per share exercisable through various times in 2007. These warrants were accounted for as described in Note 8. The fair values of all warrants were estimated using the Black-Scholes valuation method.

## **11. Income Taxes**

The provision for income taxes consists of:

|                     | <b>Year Ended December 31,</b> |              |              |
|---------------------|--------------------------------|--------------|--------------|
|                     | <b>2004</b>                    | <b>2003</b>  | <b>2002</b>  |
| Deferred:           |                                |              |              |
| Federal             | \$ 9,502,076                   | \$ 8,683,446 | \$ 7,521,820 |
| State and local     | 950,374                        | 879,474      | 861,391      |
|                     | 10,452,450                     | 9,562,920    | 8,383,211    |
| Valuation allowance | (10,452,450)                   | (9,562,920)  | (8,383,211)  |
|                     | <u>\$ -</u>                    | <u>\$ -</u>  | <u>\$ -</u>  |

The provision for income taxes varies from the amount determined by applying the U.S. federal statutory rate to income before income taxes as a result of the following:

|  | <b>Year Ended December 31,</b> |             |             |
|--|--------------------------------|-------------|-------------|
|  | <b>2004</b>                    | <b>2003</b> | <b>2002</b> |
| U.S. statutory income tax rate                       | 34.0%                          | 34.0%       | 34.0%       |
| State and local taxes, net of federal tax benefit    | 3.6%                           | 3.6%        | 3.6%        |
| Permanent differences between book and tax and other | (1.5%)                         | 0.3%        | 0.5%        |
| Research credits                                     | 2.2%                           | 2.3%        | 0.9%        |
| Valuation allowance                                  | (38.3%)                        | (40.2%)     | (39.0%)     |
| Effective income tax rate                            | <u>0.0%</u>                    | <u>0.0%</u> | <u>0.0%</u> |

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable losses, limitations imposed by Section 382 of the Internal Revenue Code and projections for future losses over periods which the deferred tax assets are deductible, management determined that a 100% valuation allowance of deferred tax assets was appropriate.

The components of the deferred tax asset are as follows:

|  | <b>December 31,</b> |                     |
|--|---------------------|---------------------|
|  | <b>2004</b>         | <b>2003</b>         |
| Current accruals                           | \$ 664,869          | \$ 1,212,564        |
| Depreciation and amortization              | 815,785             | 833,002             |
| Deferred compensation                      | 685,653             | 540,246             |
| Net operating loss carryovers              | 40,718,018          | 30,418,180          |
| Research and development credit carryovers | <u>2,697,032</u>    | <u>2,077,280</u>    |
|  | 45,581,357          | 35,081,272          |
| Valuation allowance                        | <u>(45,581,357)</u> | <u>(35,081,272)</u> |
|  | <u>\$ -</u>         | <u>\$ -</u>         |

As of December 31, 2004, the Company has federal net operating loss carryforwards of \$108,127,100. The net operating loss carryforwards will expire at various dates beginning in 2005, approximately \$2,093,000 will expire between 2005 and 2009 and approximately \$106,034,000 will expire between 2010 and 2024, if not utilized. As of December 31, 2004, the Company had federal research and development credit carryforwards of \$2,697,000, which will expire at various dates beginning in 2006 through 2024, if not utilized. Of the \$108.1 million net operating loss, approximately \$5.6 million is limited as to its use prior to December 31, 2007.

## 12. Restructuring Charge

During 2002, the Company decided to discontinue its embolic product line. This resulted in the Company incurring total restructuring expenses, included in research and development, of approximately \$267,000, consisting

primarily of employee severance costs and cancellation of contract research agreements. The Company utilized this entire accrual in 2003.

### 13. Net Loss per Share

The following is a reconciliation of the numerator (net loss) and the denominator (number of shares) used in the basic and diluted earnings per share calculations:

|  | Year Ended<br>December 31, |                |                |
|--|----------------------------|----------------|----------------|
|  | 2004                       | 2003           | 2002           |
| Basic and diluted:   |                            |                |                |
| Net loss   | \$(27,257,469)             | \$(24,036,837) | \$(21,458,658) |
| Weighted average common shares outstanding                           | 11,502,781                 | 1,424,216      | 1,326,537      |
| Less weighted average shares subject to repurchase                   | 32,471                     | 115,411        | 209,236        |
| Weighted average shares used in basic and diluted net loss per share | 11,470,310                 | 1,308,805      | 1,117,301      |
| Net loss per share   | \$ (2.38)                  | \$ (18.37)     | \$ (19.21)     |

The following table sets forth the number of common shares that could result from conversion or exercise of the following instruments as of the year ended:

|                                    | December 31, |            |            |
|------------------------------------|--------------|------------|------------|
|                                    | 2004         | 2003       | 2002       |
| Preferred stock (as if converted)  | -            | 16,959,801 | 14,343,060 |
| Options to purchase common stock   | 2,253,170    | 1,676,220  | 1,290,523  |
| Common stock subject to repurchase | 8,681        | 55,498     | 168,250    |
| Warrants                           | 1,135,526    | 894,204    | 779,022    |
|                                    | 3,397,377    | 19,585,723 | 16,580,855 |

### 14. Employee Benefit Plan

Beginning in 2002, the Company offered employees the opportunity to participate in a 401(k) plan. The Company matches employee contributions dollar for dollar up to 3% of the employee's salary during the employee's period of participation. For the years ended December 31, 2004, 2003, and 2002, the Company expensed \$361,008, \$264,965, and \$222,081, respectively, related to the plan.

### 15. Commitments and Contingencies

The Company at times becomes a party to claims in the ordinary course of business. Management believes that the ultimate resolution of pending or threatened proceedings will not have a material effect on the financial position, results of operations, or liquidity of the Company.

## 16. Quarterly Data (Unaudited)

The following tabulations reflect the unaudited quarterly results of operations for the years ended December 31, 2004 and 2003:

|                | <u>Net<br/>Sales</u> | <u>Gross<br/>Profit</u> | <u>Net<br/>Loss</u> | <u>Basic and<br/>Diluted<br/>Loss Per<br/>Share</u> |
|----------------|----------------------|-------------------------|---------------------|---|
| <b>2004</b>    |                      |                         |                     |   |
| First quarter  | \$3,073,891          | \$ 591,477              | \$(7,849,997)       | \$(5.34)  |
| Second quarter | 3,908,934            | 1,413,917               | (8,366,093)         | (5.46)  |
| Third quarter  | 5,713,611            | 2,984,093               | (5,317,489)         | (0.34)  |
| Fourth quarter | 6,120,424            | 3,155,111               | (5,723,890)         | (0.21)  |
| <b>2003</b>    |                      |                         |                     |   |
| First quarter  | \$ 386,073           | \$ (114,864)            | \$(4,905,670)       | \$(3.96)  |
| Second quarter | 1,742,967            | 660,400                 | (4,846,292)         | (3.77)  |
| Third quarter  | 1,040,932            | 439,310                 | (6,194,112)         | (4.68)  |
| Fourth quarter | 1,844,905            | (21,282)                | (8,090,763)         | (5.83)  |

## 17. Segment Information

The Company considers reporting segments in accordance with SFAS 131, *Disclosures about Segments of an Enterprise and Related Information*. The Company's system and disposable devices are developed and marketed to a broad base of hospitals in the United States and Europe. Management considers all such sales to be part of a single operating segment.

Geographic revenues are as follows:

|               | <u>Year Ended December 31,</u> |                    |                 |
|---------------|--------------------------------|--------------------|-----------------|
|               | <u>2004</u>                    | <u>2003</u>        | <u>2002</u>     |
| United States | \$12,578,610                   | \$3,577,899        | \$18,900        |
| International | 6,238,250                      | 1,436,978          | -               |
| Total         | <u>\$18,816,860</u>            | <u>\$5,014,877</u> | <u>\$18,900</u> |

All of the Company's long-lived assets are located in the United States.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

*Disclosure Controls and Procedures:* The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures provided reasonable assurance that the disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by the Company in the report that it files or submits under the Exchange Act.

*Internal Control Over Financial Reporting:* The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, also conducted an evaluation of the Company's internal control over financial reporting to determine whether any changes occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. Based on that evaluation, there has been no such change during the period covered by this report.

### **ITEM 9B. OTHER INFORMATION**

None.

## **PART III**

Certain information required by Part III is omitted from this Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the "Proxy Statement"), no later than April 30, 2005, and certain information to be included in the Proxy Statement is incorporated herein by reference.

## **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Information required by this item concerning our executive officers and directors is incorporated by reference to the information set forth in the section entitled "Directors and Executive Officers" in our Proxy Statement. Information regarding Section 16 reporting compliance is incorporated by reference to the information set forth in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement.

Our Board of Directors adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees effective August 1, 2004. Stockholders may request a free copy of our Code of Business Conduct and Ethics from our Chief Financial Officer as follows:

Stereotaxis, Inc.  
Attention: James M. Stolze  
4041 Forest Park Avenue  
St. Louis, MO 63108  
314-615-6940



To the extent required by law or the rules of the Nasdaq National Market, any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics will be promptly disclosed publicly. To the extent permitted by such requirements, we intend to make such public disclosure by posting the relevant material on our website ([www.stereotaxis.com](http://www.stereotaxis.com)) in accordance with SEC rules.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled "Executive Compensation" in our Proxy Statement.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement.

The following table summarizes certain information regarding our securities that may be issued pursuant to our equity compensation plans as of December 31, 2004.

| <u>Plan Category</u>                                       | <u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)</u> | <u>Weighted-average exercise price of outstanding options, warrants and rights</u> | <u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))(1)</u> |
|--|--|--|---|
|  | (a)  | (b)  | (c)   |
| Equity compensation plans approved by security holders     | 3,388,696  | \$6.52   | 464,372   |
| Equity compensation plans not approved by security holders | -  | -  | -   |
| Total  | <u>3,388,696</u>   | <u>\$6.52</u>  | <u>464,372</u>  |

(1) Includes 277,777 shares reserved for issuance under the 2004 Employee Stock Purchase Plan. Excludes automatic annual increases to shares by which on January 1 of 2005, 2006 and 2007, the lesser of (i) 3.25% of the total outstanding shares as of each such date or (ii) 833,333 shares will be allocated to the 2002 Stock Incentive Plan. Number of shares of common stock is subject to adjustment for changes in capitalization for stock splits, stock dividends and similar events.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The information required by this item regarding certain relationships and related transactions is incorporated by reference to the information set forth in the section titled "Certain Relationships and Related Party Transactions" in our Proxy Statement.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accounting fees and services is incorporated by reference to the information set forth in the section titled "Principal Accounting Fees and Services" in our Proxy Statement.

## **PART IV**

### **ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K

(1) Financial Statements—See Index to the Financial Statements at Item 8 of this Report on Form 10-K.

(2) The following financial statement schedule of Stereotaxis, Inc. is filed as part of this Report and should be read in conjunction with the financial statements of Stereotaxis, Inc.:

— Schedule II: Valuation and Qualifying Accounts.

All other schedules have been omitted because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

(3) Exhibits

See Exhibit Index appearing on page 86.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

STEREOTAXIS, INC.  
(Registrant)

By:           /s/ BEVIL J. HOGG            
Bevil J. Hogg, President and  
Chief Executive Officer

Date: March 28, 2005

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bevil J. Hogg and James M. Stolze, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this Annual Report on Form 10-K and any other documents and instruments incidental thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents and/or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signature   | Title   | Date           |
|---|---|----------------|
| <u>/s/ FRED A. MIDDLETON</u><br>Fred A. Middleton | Chairman of the Board of Directors  | March 28, 2005 |
| <u>/s/ BEVIL J. HOGG</u><br>Bevil J. Hogg         | President and Chief Executive Officer<br>(principal executive officer)  | March 28, 2005 |
| <u>/s/ JAMES M. STOLZE</u><br>James M. Stolze     | Vice President and Chief Financial Officer<br>(principal financial officer and principal<br>accounting officer) | March 28, 2005 |
| <u>/s/ ABHI ACHARYA</u><br>Abhi Acharya           | Director  | March 28, 2005 |
| <u>/s/ CHRISTOPHER ALAFI</u><br>Christopher Alafi | Director  | March 28, 2005 |

|   |          |                |
|---|----------|----------------|
| <u>/s/ JOHN C. APLIN</u><br>John C. Aplin               | Director | March 28, 2005 |
| <u>/s/ DAVID W. BENFER</u><br>David W. Benfer           | Director | March 28, 2005 |
| <u>/s/ RALPH G. DACEY, JR.</u><br>Ralph G. Dacey, Jr.   | Director | March 28, 2005 |
| <u>/s/ GREGORY R. JOHNSON</u><br>Gregory R. Johnson     | Director | March 28, 2005 |
| <u>/s/ WILLIAM M. KELLEY</u><br>William M. Kelley       | Director | March 28, 2005 |
| <u>/s/ RANDALL D. LEDFORD</u><br>Randall D. Ledford     | Director | March 28, 2005 |
| <u>/s/ ABHIJEET J. LELE</u><br>Abhijeet J. Lele         | Director | March 28, 2005 |
| <u>/s/ WILLIAM C. MILLS III</u><br>William C. Mills III | Director | March 28, 2005 |
| <u>/s/ DAVID J. PARKER</u><br>David J. Parker           | Director | March 28, 2005 |

## SCHEDULE II

### VALUATION AND QUALIFYING ACCOUNTS FOR THE YEARS ENDED DECEMBER 31, 2004, 2003, AND 2002

|   | Balance at<br>Beginning<br>of Year | Additions<br>Charged to<br>Cost and<br>Expenses | Deductions  | Balance at<br>the End<br>of Year |
|---|------------------------------------|---|-------------|----------------------------------|
| <b>Allowance for doubtful accounts and returns:</b> |                                    |   |             |                                  |
| Year ended December 31, 2004                        | \$116,725                          | \$151,971                                       | \$(122,473) | \$146,223                        |
| Year ended December 31, 2003                        | 1,650                              | 117,707   | (2,632)     | 116,725                          |
| Year ended December 31, 2002                        | -                                  | 3,850   | (2,200)     | 1,650                            |
| <b>Allowance for inventories valuation:</b>         |                                    |   |             |                                  |
| Year ended December 31, 2004                        | \$105,752                          | \$ 59,844                                       | \$ (52,841) | \$112,755                        |
| Year ended December 31, 2003                        | 84,580                             | 89,895  | (68,723)    | 105,752                          |
| Year ended December 31, 2002                        | -                                  | 84,580  | -           | 84,580                           |

## EXHIBIT INDEX

| <u>Number</u> | <u>Description</u>  |
|---------------|---|
| 3.1           | Restated Articles of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.   |
| 3.2           | Restated Bylaws of the Company, incorporated by reference to Exhibit 3.2 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.  |
| 4.1           | Form of Specimen Stock Certificate, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.1.   |
| 4.2           | Fourth Amended and Restated Investor Rights Agreement, dated December 17, 2002 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.2.  |
| 4.3           | Joinder Agreement to Series D-2 Preferred Stock Purchase Agreement, Fourth Amended and Restated Investor Rights Agreement and Amendment to Second Amended and Restated Stockholders' Agreement dated January 21, 2003 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.3. |
| 4.4           | Joinder and Amendment to Second Amended and Restated Stockholders' Agreement and Fourth Amended and Restated Investor Rights Agreement, dated May 27, 2003 by and among Registrant and certain stockholders incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.4.   |
| 4.5           | Second Joinder and Amendment to Second Amended and Restated Stockholders' Agreement and Fourth Amended and Restated Investor Rights Agreement, dated December 22, 2003 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.5.  |
| 4.6           | Third Joinder and Amendment to Second Amended and Restated Stockholders' Agreement and Fourth Amended and Restated Investor Rights Agreement, dated January 28, 2004 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.6.  |
| 4.7           | Form of Warrant Agreement issued to Series D-1 investors, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.7.   |
| 4.8           | Warrant Agreement issued to Silicon Valley Bank dated January 31, 2002, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.8.   |

- 4.9 Form of Warrant Agreement issued to Series D-2 investors, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.9.
- 4.10 Form of Warrant Agreement issued to Series E-2 investors, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.10.
- 4.11 Warrant Agreement issued to Silicon Valley Bank dated March 19, 2002, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.11.
- 4.12 Warrant Agreement issued to Silicon Valley Bank dated September 30, 2002, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.12.
- 10.1 1994 Stock Option Plan, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.1.
- 10.2# Form of Incentive Stock Option Agreement under the 2002 Stock Incentive Plan, , incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 10.3 2002 Stock Incentive Plan, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.2.
- 10.4# Form of Non-Qualified Stock Option Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 10.5 2004 Employee Stock Purchase Plan, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.3.
- 10.6# Form of Non-Qualified Stock Option Agreement under the 2002 Non-Employee Director Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 10.7 2002 Non-Employee Directors' Stock Plan, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.4.
- 10.8# Form of Restricted Stock Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 10.9 Employment Agreement dated June 23, 1997 between Bevil J. Hogg and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.5.

- 10.10# Form of Notice of Performance Share Award under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.5 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 10.11 Employment Agreement dated April 4, 2001 between Douglas M. Bruce and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.6.
- 10.12# Form of Subscription Agreement for the 2004 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.6 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 10.13 Employment Agreement dated February 16, 2001 between Melissa Walker and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.7.
- 10.14 Employment Agreement dated April 17, 2002 between Michael P. Kaminski and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.8.
- 10.15 Summary of Non-Employee Directors' Compensation
- 10.16 Collaboration Agreement dated June 8, 2001 between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.9.
- 10.17† Extended Collaboration Agreement dated May 27, 2003 between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.10.
- 10.18† Development and Supply Agreement dated May 7, 2002 between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.11.
- 10.19† Amendment to Development and Supply Agreement dated November 3, 2003 between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.12.
- 10.20† Supply Agreement dated July 1, 2003 between the Registrant and Magnet Sales & Manufacturing Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.13.
- 10.21 Form of Indemnification Agreement between the Registrant and its directors and executive officers, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.14.
- 10.22 Lease, having an effective date of August 15, 2001, between the Registrant and Emerging Technologies Building II, LLC, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.15.



- 10.23† Letter Agreement, dated September 12, 2003, between the Registrant and Philips Medizin Systeme G.m.b.H., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.16.
- 10.24 Letter Agreement and Employment Agreement dated May 26, 2004 between James M. Stolze and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.17.
- 10.25† Software Distribution Agreement dated March 3, 2004 between the Registrant and Siemens Aktiengesellschaft, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.18.
- 10.26† Third Party Service Agreement dated August 5, 2002 between the Registrant and Siemens Medical Solutions USA, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.19.
- 10.27† Research Agreement between the Registrant, Siemens AG and Landesbetrieb Krankenhaus, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.20.
- 10.28 Loan and Security Agreement dated January 31, 2002 between the Registrant and Silicon Valley Bank, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.21.
- 10.29 Loan Modification Agreement dated May 14, 2002 between the Registrant and Silicon Valley Bank, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.22.
- 10.30 Second Loan Modification Agreement dated July 11, 2002 between the Registrant and Silicon Valley Bank, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.23.
- 10.31 Loan and Security Agreement dated September 30, 2002 between the Registrant and Silicon Valley Bank, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.24.
- 10.32 Second Loan Modification Agreement dated September 30, 2002 to Equipment Loan and Security Agreement dated January 31, 2002 and Third Loan Modification Agreement to Revolving Loan and Security Agreement dated March 19, 2002, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.25.
- 10.33 Third Loan Modification Agreement dated December 31, 2002 to Equipment Loan and Security Agreement dated January 31, 2002 and Fourth Loan Modification Agreement to Revolving Loan and Security Agreement dated March 19, 2002 and First Loan Modification Agreement to Equipment Loan and Security Agreement dated September 30, 2002 between the Registrant and Silicon Valley Bank, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.26.
- 10.34 Fourth Loan Modification Agreement dated April 2003 to Equipment Loan and Security Agreement dated January 31, 2002 and Fifth Loan Modification Agreement to Revolving Loan and Security Agreement dated

March 19, 2002 and Second Loan Modification Agreement to Equipment Loan and Security Agreement dated September 30, 2002, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.27.

- 10.35 Loan and Security Agreement dated April 30, 2004 between the Registrant and Silicon Valley Bank, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.28.
- 10.36† Distributor Agreement dated September 17, 2003 between the Registrant and AB Medica, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.29.
- 10.37 Promissory Note dated November 20, 2001 by Douglas M. Bruce payable to the order of Stereotaxis, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.30.
- 10.38† Japanese Market Development Agreement dated May 18, 2004 between the Registrant, Siemens Aktiengesellschaft and Siemens Asahi Medical Technologies Ltd., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 10.32.
- 10.39\* Office Lease dated November 15, 2004 between the Registrant and Cortex West Development I, LLC
- 23.1 Consent of Ernst & Young LLP
- 31.1 Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
- 31.2 Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer).
- 32.1 Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
- 32.2 Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer)

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# Indicates management contract or compensatory plan

† Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

\* Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements (Form S-8) pertaining to the Stereotaxis, Inc. 2004 Employee Stock Purchase Plan, the Stereotaxis, Inc. 2002 Stock Incentive Plan, the Stereotaxis, Inc. 2002 Non-Employee Directors' Stock Plan, and the Stereotaxis, Inc. 1994 Stock Plan (No. 333-115253) of our report dated February 18, 2005, with respect to the consolidated financial statements and schedule of Stereotaxis, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

St. Louis, Missouri  
March 22, 2005

**Certification of Principal Executive Officer**

I, Bevil J. Hogg, certify that:

1. I have reviewed this annual report on Form 10-K of Stereotaxis, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Reserved - not effective
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2005

/s/ BEVIL J. HOGG

Bevil J. Hogg  
President and Chief Executive Officer  
Stereotaxis, Inc.  
(Principal Executive Officer)

Certification of Principal Financial Officer

I, James M. Stolze, certify that:

1. I have reviewed this annual report on Form 10-K of Stereotaxis, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Reserved - not effective
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2005

/s/ JAMES M. STOLZE  
James M. Stolze  
Vice President and Chief Financial Officer  
Stereotaxis, Inc.  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Stereotaxis, Inc. (the "Company") on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Bevil J. Hogg, President and Chief Executive Officer of the Company, certify, pursuant to Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2005

/s/ BEVIL J. HOGG  
Bevil J. Hogg  
President and Chief Executive Officer  
Stereotaxis, Inc.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Stereotaxis, Inc. (the "Company") on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James M. Stolze, Vice President and Chief Financial Officer of the Company, certify, pursuant to Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2005

/s/ JAMES M. STOLZE

James M. Stolze

Vice President and Chief Financial Officer

Stereotaxis, Inc.